

US3672187 (Prod: Coastal Carolina Research Center)

Generated By: KC Joubran

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All time stamps listed in this document are displayed in GMT

US3672187

Form: Participant Creation

Data signed: (b) (4) 05 Mar 2021 17:59:19

Generated On: 10 Jun 2021 09:22:10

[Participant ID](#)

US3672187

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

US3672187

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 20:01:45

Generated On: 10 Jun 2021 09:22:10

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 20:01:45

Generated On: 10 Jun 2021 09:22:10

Date of Birth (MMM yyyy)	(b) (6) 1948
Age	72
Age Units	YEARS
Age (Derived)	72
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 20:01:45

Generated On: 10 Jun 2021 09:22:10

Date of Informed Consent (<i>dd MMM yyyy</i>)	19 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input checked="" type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify _____	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number _____	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 20:01:45

Generated On: 10 Jun 2021 09:22:10

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 20:01:45

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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 20:01:45

Generated On: 10 Jun 2021 09:22:10

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

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 20:01:45

Generated On: 10 Jun 2021 09:22:10

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	19 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	10:32 (24 HR)
Vital Signs Date and Time (derived)	19 AUG 2020 10:32
Height (<i>xxx.x</i>)	170.0 cm
Weight (<i>xxx.x</i>)	105.7 kg
BMI (<i>xxx.x</i>)	36.57439 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 20:01:45

Generated On: 10 Jun 2021 09:22:10

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 20:01:45

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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 20:01:45

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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	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 20:01:45

Generated On: 10 Jun 2021 09:22:10

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 20:01:45

Generated On: 10 Jun 2021 09:22:10

What was the date of randomization? (dd MMM yyyy) 19 AUG 2020

What was the participant's randomization number? 186989

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 20:01:45

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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 20:01:45

Generated On: 10 Jun 2021 09:22:10

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	19 AUG 2020
Time of assessment (00:00-23:59)	10:32 (24 HR)
Vital Signs Date and Time (derived)	19 AUG 2020 10:32
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	53 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	157 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	97 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 20:01:45

Generated On: 10 Jun 2021 09:22:10

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	19 AUG 2020
Time of assessment (00:00-23:59)	11:42 (24 HR)
Vital Signs Date and Time (derived)	19 AUG 2020 11:42
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	50 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	156 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: Physical Examination

Data signed: (b) (4) 15 Feb 2021 20:01:45

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 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: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 20:01:45

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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) 19 AUG 2020

What was the treatment time? (00:00-23:59) 11:06 (24 HR)

Treatment Date and Time (derived) 19 AUG 2020 11:06

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 20:01:45

Generated On: 10 Jun 2021 09:22:10

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	19 AUG 2020
Collection time (00:00-23:59)	10:43 (24 HR)
Collection date and time (derived)	19 AUG 2020 10:43

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 20:01:45

Generated On: 10 Jun 2021 09:22:10

Collection date (dd MMM yyyy)			19 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:20	19 AUG 2020 10:20
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 20:01:45

Generated On: 10 Jun 2021 09:22:10

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: 10 Jun 2021 09:22:10

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 AUG 2020 11:40

PC Open Date & Time

19 AUG 2020 11:26

PC Close Date & Time

19 AUG 2020 13:56

US3672187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:22:10

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	19 AUG 2020 21:32
PC Open Date & Time	19 AUG 2020 14:51
PC Close Date & Time	20 AUG 2020 11:59

US3672187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:22:10

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

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

20 AUG 2020 21:12

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3672187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:22:10

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

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 AUG 2020 19:03

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3672187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:22:10

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

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 AUG 2020 19:14

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3672187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:22:10

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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:22:10

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

98.0 °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

24 AUG 2020 19:18

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3672187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °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

25 AUG 2020 20:45

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3672187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:22:10

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

19 AUG 2020 11:41

PC Open Date & Time

19 AUG 2020 11:26

PC Close Date & Time

19 AUG 2020 13:56

US3672187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:22:10

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

19 AUG 2020 21:33

PC Open Date & Time

19 AUG 2020 14:51

PC Close Date & Time

20 AUG 2020 11:59

US3672187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:22:10

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

20 AUG 2020 21:12

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3672187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:22:10

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

21 AUG 2020 19:03

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3672187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:22:10

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

22 AUG 2020 19:14

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3672187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:22:10

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 ☐

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the
ruler provided.

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

Yes ☐

No ☐

Please record - **SWELLING/HARDNESS AT INJECTION SITE
(in mm)**

Measure the largest size across any injection site swelling/hardness
with the ruler provided.

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

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3672187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:22:10

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

24 AUG 2020 19:18

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3672187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:22:10

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

25 AUG 2020 20:45

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:22:10

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 ☐

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:22:10

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

No ☒

Yes ☐

PC Time stamp	19 AUG 2020 11:41
PC Open Date & Time	19 AUG 2020 11:26
PC Close Date & Time	19 AUG 2020 13:56

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:22:10

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 ☐

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:22:10

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

No ☒

Yes ☐

PC Time stamp	19 AUG 2020 21:33
PC Open Date & Time	19 AUG 2020 14:51
PC Close Date & Time	20 AUG 2020 11:59

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:22:10

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 ☒

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:22:10

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

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:22:10

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)

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:22:10

Yes <input type="checkbox"/>	
PC Time stamp	21 AUG 2020 19:04
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:22:10

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 ☒

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:22:10

Yes <input type="checkbox"/>	
PC Time stamp	22 AUG 2020 19:15
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:22:10

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)

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Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:22:10

Yes ☐

PC Time stamp

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:22:10

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)

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:22:10

Yes <input type="checkbox"/>	
PC Time stamp	24 AUG 2020 19:19
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:22:10

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

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EAB) (1725)

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:22:10

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 20:45
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3672187

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 20:01:45

Generated On: 10 Jun 2021 09:22:10

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3672187

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 20:01:45

Generated On: 10 Jun 2021 09:22:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672187

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 20:01:45

Generated On: 10 Jun 2021 09:22:10

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

07 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3672187

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 20:01:45

Generated On: 10 Jun 2021 09:22:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672187

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 20:01:45

Generated On: 10 Jun 2021 09:22:10

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3672187

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 20:01:45

Generated On: 10 Jun 2021 09:22:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672187

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 20:01:45

Generated On: 10 Jun 2021 09:22:10

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3672187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 20:01:45

Generated On: 10 Jun 2021 09:22:10

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	21 SEP 2020
Time of assessment (00:00-23:59)	10:20 (24 HR)
Vital Signs Date and Time (derived)	21 SEP 2020 10:20
Temperature (xxx.x)	98 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	158 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	120 mmHg
Diastolic Blood Pressure units	MMHG

US3672187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 20:01:45

Generated On: 10 Jun 2021 09:22:10

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

US3672187

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 20:01:45

Generated On: 10 Jun 2021 09:22:10

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 SEP 2020

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

US3672187

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 20:01:45

Generated On: 10 Jun 2021 09:22:10

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

ELEVATED DIASTOLIC BLOOD PRESSURE (GRADE 3).

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? _____

US3672187

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 20:01:45

Generated On: 10 Jun 2021 09:22:10

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

21 SEP 2020

Collection time (00:00-23:59)

10:47 (24 HR)

Collection date and time (derived)

21 SEP 2020 10:47

US3672187

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 20:01:45

Generated On: 10 Jun 2021 09:22:10

Collection date (dd MMM yyyy)			21 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:42	21 SEP 2020 10:42
Nasopharyngeal Swab 2	No		

US3672187

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 20:01:45

Generated On: 10 Jun 2021 09:22:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672187

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 20:01:45

Generated On: 10 Jun 2021 09:22:10

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3672187

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 20:01:45

Generated On: 10 Jun 2021 09:22:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672187

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 20:01:45

Generated On: 10 Jun 2021 09:22:10

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

6 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3672187

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 20:01:45

Generated On: 10 Jun 2021 09:22:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672187

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 20:01:45

Generated On: 10 Jun 2021 09:22:10

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3672187

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 20:01:45

Generated On: 10 Jun 2021 09:22:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672187

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 20:01:45

Generated On: 10 Jun 2021 09:22:10

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3672187

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 20:01:45

Generated On: 10 Jun 2021 09:22:10

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	16 OCT 2020
Time of assessment (00:00-23:59)	09:51 (24 HR)
Vital Signs Date and Time (derived)	16 OCT 2020 09:51
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3672187

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 20:01:45

Generated On: 10 Jun 2021 09:22:10

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.

US3672187

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 20:01:45

Generated On: 10 Jun 2021 09:22:10

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

16 OCT 2020

Collection time (00:00-23:59)

10:15 (24 HR)

Collection date and time (derived)

16 OCT 2020 10:15

US3672187

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 20:01:45

Generated On: 10 Jun 2021 09:22:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

19 OCT 2020 09:47:40

Patient Cloud Open Date & Time

19 OCT 2020 00:01

Patient Cloud Close Date & Time

23 OCT 2020 23:59

US3672187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

26 OCT 2020 15:51:47

Patient Cloud Open Date & Time

26 OCT 2020 00:01

Patient Cloud Close Date & Time

30 OCT 2020 23:59

US3672187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 NOV 2020 21:33:38
Patient Cloud Open Date & Time	02 NOV 2020 00:01
Patient Cloud Close Date & Time	06 NOV 2020 23:59

US3672187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 NOV 2020 10:22:10
Patient Cloud Open Date & Time	16 NOV 2020 00:01
Patient Cloud Close Date & Time	20 NOV 2020 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 NOV 2020 14:24:44
Patient Cloud Open Date & Time	20 NOV 2020 00:01
Patient Cloud Close Date & Time	24 NOV 2020 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

27 NOV 2020 17:55:41

Patient Cloud Open Date & Time

27 NOV 2020 00:01

Patient Cloud Close Date & Time

01 DEC 2020 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

04 DEC 2020 20:42:59

Patient Cloud Open Date & Time

04 DEC 2020 00:01

Patient Cloud Close Date & Time

08 DEC 2020 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

12 DEC 2020 21:32:36

Patient Cloud Open Date & Time

11 DEC 2020 00:01

Patient Cloud Close Date & Time

15 DEC 2020 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

18 DEC 2020 13:49:45

Patient Cloud Open Date & Time

18 DEC 2020 00:01

Patient Cloud Close Date & Time

22 DEC 2020 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

28 DEC 2020 11:59:13

Patient Cloud Open Date & Time

25 DEC 2020 00:01

Patient Cloud Close Date & Time

29 DEC 2020 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 JAN 2021 09:17:10

Patient Cloud Open Date & Time

01 JAN 2021 00:01

Patient Cloud Close Date & Time

05 JAN 2021 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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 00:21:41

Patient Cloud Open Date & Time

08 JAN 2021 00:01

Patient Cloud Close Date & Time

12 JAN 2021 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

16 JAN 2021 02:23:17

Patient Cloud Open Date & Time

15 JAN 2021 00:01

Patient Cloud Close Date & Time

19 JAN 2021 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 JAN 2021 14:09:24
Patient Cloud Open Date & Time	22 JAN 2021 00:01
Patient Cloud Close Date & Time	26 JAN 2021 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

29 JAN 2021 23:42:11

Patient Cloud Open Date & Time

29 JAN 2021 00:01

Patient Cloud Close Date & Time

02 FEB 2021 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

05 FEB 2021 07:49:43

Patient Cloud Open Date & Time

05 FEB 2021 00:01

Patient Cloud Close Date & Time

09 FEB 2021 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

13 FEB 2021 07:26:18

Patient Cloud Open Date & Time

12 FEB 2021 00:01

Patient Cloud Close Date & Time

16 FEB 2021 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

19 FEB 2021 01:55:23

Patient Cloud Open Date & Time

19 FEB 2021 00:01

Patient Cloud Close Date & Time

23 FEB 2021 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

26 FEB 2021 16:04:26

Patient Cloud Open Date & Time

26 FEB 2021 00:01

Patient Cloud Close Date & Time

02 MAR 2021 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	05 MAR 2021 08:29:12
Patient Cloud Open Date & Time	05 MAR 2021 00:01
Patient Cloud Close Date & Time	09 MAR 2021 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT	DAY 208
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	14 MAR 2021 00:06:41
Patient Cloud Open Date & Time	12 MAR 2021 00:01
Patient Cloud Close Date & Time	16 MAR 2021 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

19 MAR 2021 00:21:44

Patient Cloud Open Date & Time

19 MAR 2021 00:01

Patient Cloud Close Date & Time

23 MAR 2021 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

27 MAR 2021 15:29:01

Patient Cloud Open Date & Time

26 MAR 2021 00:01

Patient Cloud Close Date & Time

30 MAR 2021 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

02 APR 2021 10:06:10

Patient Cloud Open Date & Time

02 APR 2021 00:01

Patient Cloud Close Date & Time

06 APR 2021 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

10 APR 2021 20:24:48

Patient Cloud Open Date & Time

09 APR 2021 00:01

Patient Cloud Close Date & Time

13 APR 2021 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

16 APR 2021 23:06:04

Patient Cloud Open Date & Time

16 APR 2021 00:01

Patient Cloud Close Date & Time

20 APR 2021 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

23 APR 2021 00:13:40

Patient Cloud Open Date & Time

23 APR 2021 00:01

Patient Cloud Close Date & Time

27 APR 2021 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

30 APR 2021 07:14:02

Patient Cloud Open Date & Time

30 APR 2021 00:01

Patient Cloud Close Date & Time

04 MAY 2021 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

[Patient Cloud Open Date & Time](#)

07 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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 ☐

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

[Patient Cloud Open Date & Time](#)

14 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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 ☐

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

[Patient Cloud Open Date & Time](#)

21 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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 ☐

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

[Patient Cloud Open Date & Time](#)

28 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

[Patient Cloud Open Date & Time](#)

04 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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 ☐

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

[Patient Cloud Open Date & Time](#)

11 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

DAY 306

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

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

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

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

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

Fever (Temperature \geq 100.4°F/38°C) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

[Patient Cloud Open Date & Time](#)

18 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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 ☐

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

[Patient Cloud Open Date & Time](#)

25 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

[Patient Cloud Open Date & Time](#)

02 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

DAY 327

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

[Patient Cloud Open Date & Time](#)

09 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

[Patient Cloud Open Date & Time](#)

16 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2021 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

[Patient Cloud Open Date & Time](#)

23 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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 ☐

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

[Patient Cloud Open Date & Time](#)

06 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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 ☐

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

[Patient Cloud Open Date & Time](#)

13 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

17 AUG 2021 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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°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 ☐

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

Patient Cloud Open Date & Time	20 AUG 2021 00:01
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Patient Cloud Close Date & Time	24 AUG 2021 23:59
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US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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 ☐

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

[Patient Cloud Open Date & Time](#)

27 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

[Patient Cloud Open Date & Time](#)

03 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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 ☐

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

[Patient Cloud Open Date & Time](#)

10 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

DAY 397

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

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

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

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

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

Fever (Temperature \geq 100.4°F/38°C) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

[Patient Cloud Open Date & Time](#)

17 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

[Patient Cloud Open Date & Time](#)

24 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

[Patient Cloud Open Date & Time](#)

01 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2021 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

[Patient Cloud Open Date & Time](#)

08 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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 ☐

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

Patient Cloud Open Date & Time	15 OCT 2021 00:01
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Patient Cloud Close Date & Time	19 OCT 2021 23:59
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US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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 ☐

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

Patient Cloud Open Date & Time	22 OCT 2021 00:01
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Patient Cloud Close Date & Time	26 OCT 2021 23:59
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US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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 ☐

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

[Patient Cloud Open Date & Time](#)

29 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

[Patient Cloud Open Date & Time](#)

05 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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°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 ☐

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

[Patient Cloud Open Date & Time](#)

12 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

16 NOV 2021 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

[Patient Cloud Open Date & Time](#)

19 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

[Patient Cloud Open Date & Time](#)

26 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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 ☐

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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 ☐

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 DEC 2021 00:01
Patient Cloud Close Date & Time	14 DEC 2021 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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 ☐

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

[Patient Cloud Open Date & Time](#)

17 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

21 DEC 2021 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	24 DEC 2021 00:01
Patient Cloud Close Date & Time	28 DEC 2021 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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 ☐

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

[Patient Cloud Open Date & Time](#)

31 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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 ☐

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

[Patient Cloud Open Date & Time](#)

07 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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 ☐

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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 ☐

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

[Patient Cloud Open Date & Time](#)

21 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

[Patient Cloud Open Date & Time](#)

28 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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 ☐

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

[Patient Cloud Open Date & Time](#)

04 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

DAY 544

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

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

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

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

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

Fever (Temperature \geq 100.4°F/38°C) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

[Patient Cloud Open Date & Time](#)

11 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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 ☐

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

[Patient Cloud Open Date & Time](#)

18 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

22 FEB 2022 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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°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 ☐

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

[Patient Cloud Open Date & Time](#)

25 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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°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 ☐

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

[Patient Cloud Open Date & Time](#)

04 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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 ☐

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

[Patient Cloud Open Date & Time](#)

11 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAR 2022 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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 ☐

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

[Patient Cloud Open Date & Time](#)

18 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAR 2022 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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 ☐

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

[Patient Cloud Open Date & Time](#)

25 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAR 2022 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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 ☐

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

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 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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 ☐

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

[Patient Cloud Open Date & Time](#)

15 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

19 APR 2022 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

Patient Cloud Open Date & Time	22 APR 2022 00:01
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Patient Cloud Close Date & Time	26 APR 2022 23:59
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US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

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 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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 ☐

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

[Patient Cloud Open Date & Time](#)

06 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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 ☐

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

[Patient Cloud Open Date & Time](#)

13 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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 ☐

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

[Patient Cloud Open Date & Time](#)

20 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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 ☐

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

[Patient Cloud Open Date & Time](#)

27 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

DAY 656

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

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

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

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

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

Fever (Temperature \geq 100.4°F/38°C) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

[Patient Cloud Open Date & Time](#)

03 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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 ☐

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

[Patient Cloud Open Date & Time](#)

10 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2022 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

[Patient Cloud Open Date & Time](#)

17 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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 ☐

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

[Patient Cloud Open Date & Time](#)

24 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2022 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

DAY 684

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

[Patient Cloud Open Date & Time](#)

01 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

[Patient Cloud Open Date & Time](#)

08 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2022 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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 ☐

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 JUL 2022 00:01
Patient Cloud Close Date & Time	19 JUL 2022 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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 ☐

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

[Patient Cloud Open Date & Time](#)

22 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2022 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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 ☐

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

[Patient Cloud Open Date & Time](#)

29 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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 ☐

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

[Patient Cloud Open Date & Time](#)

05 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2022 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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°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 ☐

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

Patient Cloud Open Date & Time	12 AUG 2022 00:01
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Patient Cloud Close Date & Time	16 AUG 2022 23:59
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US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

DAY 733

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

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

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

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

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

Fever (Temperature \geq 100.4°F/38°C) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

[Patient Cloud Open Date & Time](#)

19 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2022 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

[Patient Cloud Open Date & Time](#)

26 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2022 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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 ☐

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

[Patient Cloud Open Date & Time](#)

02 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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 ☐

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

[Patient Cloud Open Date & Time](#)

09 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

[Patient Cloud Open Date & Time](#)

16 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2022 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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 ☐

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

[Patient Cloud Open Date & Time](#)

23 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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 ☐

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

[Patient Cloud Open Date & Time](#)

30 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2022 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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 ☐

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

18 OCT 2022 23:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

[Patient Cloud Open Date & Time](#)

21 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

25 OCT 2022 23:59

US3672187

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:22:10

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 21:06:06

US3672187

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 17:59:21

Generated On: 10 Jun 2021 09:22:10

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 16 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3672187

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 17:59:21

Generated On: 10 Jun 2021 09:22:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672187

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 17:59:21

Generated On: 10 Jun 2021 09:22:10

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

US3672187

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 17:59:21

Generated On: 10 Jun 2021 09:22:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672187

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 17:59:21

Generated On: 10 Jun 2021 09:22:10

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3672187

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 17:59:21

Generated On: 10 Jun 2021 09:22:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672187

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 17:59:21

Generated On: 10 Jun 2021 09:22:10

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

US3672187

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 17:59:21

Generated On: 10 Jun 2021 09:22:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672187

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 15:08:57

Generated On: 10 Jun 2021 09:22:10

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

Visit date (dd MMM yyyy)	31 MAR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3672187

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 15:08:57

Generated On: 10 Jun 2021 09:22:10

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) _____

US3672187

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 15:08:26

Generated On: 10 Jun 2021 09:22:10

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.

US3672187

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 15:08:26

Generated On: 10 Jun 2021 09:22:10

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

31 MAR 2021

Collection time (00:00-23:59)

13:10 (24 HR)

Collection date and time (derived)

31 MAR 2021 13:10

US3672187

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 15:08:26

Generated On: 10 Jun 2021 09:22:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672187

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:10

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

US3672187

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:10

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3672187

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:22:10

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

US3672187

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 09:22:10

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3672187

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

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 17:59:19

Generated On: 10 Jun 2021 09:22:10

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

Visit date (dd MMM yyyy)	25 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3672187

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

Form: Unblinding

Data signed: (b) (4) 16 Apr 2021 15:08:26

Generated On: 10 Jun 2021 09:22:10

Date of updated informed consent (<i>dd MMM yyyy</i>)	25 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	25 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input type="radio"/> Not Administered <input checked="" type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3672187

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 05 Mar 2021 17:59:19

Generated On: 10 Jun 2021 09:22:10

Height	170.0 cm
Weight	105.7 kg
BMI (xxx.x)	36.57439

US3672187

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Mar 2021 17:59:19

Generated On: 10 Jun 2021 09:22:10

Height	170.0 cm
Weight	105.7 kg
BMI (xxx.x)	36.57439
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	25 JAN 2021
Time of assessment (00:00-23:59)	09:17 (24 HR)
Vital Signs Date and Time (derived)	25 JAN 2021 09:17
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify _____	
Pulse (xxx)	86 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3672187

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Mar 2021 17:59:19

Generated On: 10 Jun 2021 09:22:10

Height	170.0 cm
Weight	105.7 kg
BMI (xxx.x)	36.57439
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	25 JAN 2021
Time of assessment (00:00-23:59)	10:20 (24 HR)
Vital Signs Date and Time (derived)	25 JAN 2021 10:20
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	92 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG

US3672187

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

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 17:59:19

Generated On: 10 Jun 2021 09:22:10

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

25 JAN 2021

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

US3672187

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

Form: Exposure

Data signed: (b) (4) 05 Mar 2021 17:59:19

Generated On: 10 Jun 2021 09:22:10

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) 25 JAN 2021

What was the treatment time? (00:00-23:59) 09:42 (24 HR)

Treatment Date and Time (derived) 25 JAN 2021 09:42

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

US3672187

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 17:59:19

Generated On: 10 Jun 2021 09:22:10

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

25 JAN 2021

Collection time (00:00-23:59)

09:32 (24 HR)

Collection date and time (derived)

25 JAN 2021 09:32

US3672187

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 05 Mar 2021 17:59:19

Generated On: 10 Jun 2021 09:22:10

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	25 JAN 2021
Collection time (00:00 - 23:59)	09:10
Collection Date and Time (derived)	25 JAN 2021 09:10

US3672187

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

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 17:59:19

Generated On: 10 Jun 2021 09:22:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672187

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 17:59:21

Generated On: 10 Jun 2021 09:22:10

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3672187

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 17:59:21

Generated On: 10 Jun 2021 09:22:10

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3672187

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 15:08:26

Generated On: 10 Jun 2021 09:22:10

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	05 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3672187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Apr 2021 15:08:26

Generated On: 10 Jun 2021 09:22:10

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	05 MAR 2021
Time of assessment (00:00-23:59)	09:39 (24 HR)
Vital Signs Date and Time (derived)	05 MAR 2021 09:39
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	90 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3672187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Apr 2021 15:08:26

Generated On: 10 Jun 2021 09:22:10

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	05 MAR 2021
Time of assessment (00:00-23:59)	10:51 (24 HR)
Vital Signs Date and Time (derived)	05 MAR 2021 10:51
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	97 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

US3672187

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 15:08:26

Generated On: 10 Jun 2021 09:22:10

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

05 MAR 2021

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

US3672187

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 16 Apr 2021 15:08:26

Generated On: 10 Jun 2021 09:22:10

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) 05 MAR 2021

What was the treatment time? (00:00-23:59) 10:15 (24 HR)

Treatment Date and Time (derived) 05 MAR 2021 10:15

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

US3672187

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 15:08:26

Generated On: 10 Jun 2021 09:22:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672187

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 15:08:26

Generated On: 10 Jun 2021 09:22:10

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3672187

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 15:08:26

Generated On: 10 Jun 2021 09:22:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672187

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 15:08:26

Generated On: 10 Jun 2021 09:22:10

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	6 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3672187

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 15:08:26

Generated On: 10 Jun 2021 09:22:10

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) _____

US3672187

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 15:08:26

Generated On: 10 Jun 2021 09:22:10

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.

US3672187

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 15:08:26

Generated On: 10 Jun 2021 09:22:10

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	6 APR 2021
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Collection time (00:00-23:59)	10:07 (24 HR)
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Collection date and time (derived)	6 APR 2021 10:07
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US3672187

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 05 Mar 2021 17:59:19

Generated On: 10 Jun 2021 09:22:10

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3672187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:10

AEID	
Adverse event	ELEVATED DIASTOLIC BLOOD PRESSURE
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	21 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	17 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3672187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:10

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

US3672187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:10

AEID	USA-US116-2021-MRNA-1273-P30 1000009
Adverse event	PNEUMONIA RIGHT LUNG
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	6 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	9 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	6 MAR 2021
Hospital Discharge Date (dd MMM yyyy)	9 MAR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3672187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:10

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	AT PATIENT'S OL D36 TC IT WAS MENTIONED PATIENT HAD RECENTLY SPENT TIME IN THE HOSPITAL AT THE VA FOR PNEUMONIA IN THE RIGHT LUNG. PATIENT WAS TREATED WITH CEFDINIR AND RELEASED AFTER A FULL RECOVERY.
Serious Adverse Event Derived (CSA Programming Field Only)	1

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3672187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:10

Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

US3672187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 05 Mar 2021 17:59:19

Generated On: 10 Jun 2021 09:22:10

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

Yes ☒

No ☐

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

US3672187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 21:40:12

Generated On: 10 Jun 2021 09:22:10

Name of Medication ASPRIN

Prophylaxis Yes ☒
No ☐

Indication CARDIAC PROPHYLAXIS

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3672187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 21:40:12

Generated On: 10 Jun 2021 09:22:10

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3672187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Apr 2021 21:40:12

Generated On: 10 Jun 2021 09:22:10

Name of Medication LIPITOR

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3672187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Apr 2021 21:40:12

Generated On: 10 Jun 2021 09:22:10

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		26 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3672187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 08 Apr 2021 21:40:12

Generated On: 10 Jun 2021 09:22:10

Name of Medication CEFDINIR

Prophylaxis Yes ☐
No ☒

Indication PNEUMONIA RIGHT LUNG

Dose per administration 300

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

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 08 Apr 2021 21:40:12

Generated On: 10 Jun 2021 09:22:10

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	6 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	7 MAR 2021	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input checked="" type="radio"/>	

US3672187

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 08 Apr 2021 21:40:12

Generated On: 10 Jun 2021 09:22:10

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3672187

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 05 Mar 2021 17:59:19

Generated On: 10 Jun 2021 09:22:10

Date of dosing discontinuation (dd MMM yyyy)	21 SEP 2020
--	-------------

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

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify	AE #1
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US3672187

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:22:10

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 ☐

US3672187

Folder: SAE USA-US116-2021-MRNA-1273-P301000009

Form: Safety Report Form

Data signed: (b) (4) 22 Apr 2021 18:35:41

Generated On: 10 Jun 2021 09:22:10

SAEID	USA-US116-2021-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CYNTHIA
Investigator's Last Name	STROUT
Site Address: Street	4920 O HEAR AVE SUITE 101
Site Address: City	MOUNT PLEASANT
Site Address: State	SC
Site Address: Postal Code	29464
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3672187

Folder: SAE USA-US116-2021-MRNA-1273-P301000009

Form: Safety Report Form (1)

Data signed: (b) (4) 22 Apr 2021 18:35:41

Generated On: 10 Jun 2021 09:22:10

SAEID	USA-US116-2021-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CYNTHIA
Investigator's Last Name	STROUT
Site Address: Street	4920 O HEAR AVE SUITE 101
Site Address: City	MOUNT PLEASANT
Site Address: State	SC
Site Address: Postal Code	29464
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	16/MAR/2021 10:39
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3672187

Folder: SAE USA-US116-2021-MRNA-1273-P301000009

Form: Safety Report Form (2)

Data signed: (b) (4) 22 Apr 2021 18:35:41

Generated On: 10 Jun 2021 09:22:10

SAEID	USA-US116-2021-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CYNTHIA
Investigator's Last Name	STROUT
Site Address: Street	4920 O HEAR AVE SUITE 101
Site Address: City	MOUNT PLEASANT
Site Address: State	SC
Site Address: Postal Code	29464
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	12/APR/2021 10:03
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3672187 (Prod: Coastal Carolina Research Center)

US3672187

Form: Participant Creation

Generated On: 10 Jun 2021 09:22:10

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered 'US3672187'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 14:34:24

US3672187

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:22:10

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 15:07:14

US3672187

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered '19 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 14:34:25

US3672187

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:22:10

[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 18:03:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 15:07:14

US3672187

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:22:10

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:57
User entered 'SCRN'	System	19 Aug 2020 15:07:14

US3672187

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered (b) (6) 1948'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 14:34:26

US3672187

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:22:10

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered '72'	(b) (4), (b) (6)	19 Aug 2020 15:07:29

US3672187

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:22:10

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:57
User entered 'YEARS'	System	19 Aug 2020 15:07:29

US3672187

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:22:10

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:57
User entered '72'	System	19 Aug 2020 15:07:40

US3672187

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:22:10

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered 'Male (M)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 15:07:29

US3672187

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:22:10

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	19 Aug 2020 15:07:29

US3672187

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:22:10

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered 'I'	(b) (4), (b) (6)	19 Aug 2020 15:07:29

US3672187

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:22:10

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 15:07:29

US3672187

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:22:10

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 15:07:29

US3672187

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:22:10

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 15:07:29

US3672187

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:22:10

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 15:07:29

US3672187

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:22:10

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 15:07:29

US3672187

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:22:10

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 15:07:29

US3672187

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:22:10

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 15:07:29

US3672187

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:22:10

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 15:07:29

US3672187

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:22:10

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered '19 Aug 2020'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 15:07:40

US3672187

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:57
User entered 'Aug 2020'	System	19 Aug 2020 15:07:40

US3672187

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:57
User entered '2020'	System	19 Aug 2020 15:07:40

US3672187

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:22:10

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered 'Amendment 2 (2)'	(b) (4), (b) (6)	19 Aug 2020 15:07:40

US3672187

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 15:07:40

US3672187

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 15:07:40

US3672187

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:22:10

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 15:07:40

US3672187

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:22:10

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 15:07:40

US3672187

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:22:10

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 14:34:25

US3672187

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:22:10

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:57
User entered 'I'	System	19 Aug 2020 15:07:43

US3672187

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 15:07:43

US3672187

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:22:10

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	28 Sep 2020 18:35:30
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 12:46:51

US3672187

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:22:10

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
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)	28 Sep 2020 18:37:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 18:37:50
Data point term sent to Coder	System	28 Sep 2020 18:36:40
User entered 'hypertension'	(b) (4), (b) (6)	28 Sep 2020 18:35:51

US3672187

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered 'un UNK 2019'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:35:51

US3672187

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:22:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:35:51

US3672187

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:22:10

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:35:51

US3672187

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:35:51

US3672187

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:22:10

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:35:51

US3672187

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:57
User entered 'Jan 2019'	System	28 Sep 2020 18:35:51

US3672187

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:57
User entered '2019'	System	28 Sep 2020 18:35:51

US3672187

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:57
User entered empty.	System	28 Sep 2020 18:35:51

US3672187

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:57
User entered empty.	System	28 Sep 2020 18:35:51

US3672187

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 12:47:25

US3672187

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered '19 Aug 2020'	(b) (4), (b) (6)	21 Aug 2020 12:47:25

US3672187

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered '10:32'	(b) (4), (b) (6)	21 Aug 2020 12:47:25

US3672187

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:57
User entered '19 Aug 2020 10:32'	System	21 Aug 2020 12:47:25

US3672187

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered '170.0' cm	(b) (4) (b) (4), (b) (6)	21 Aug 2020 12:47:25
DataPoint set to visible.	System	19 Aug 2020 15:07:43

US3672187

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered '105.7' kg	(b) (4) (b) (4), (b) (6)	21 Aug 2020 12:47:25
DataPoint set to visible.	System	19 Aug 2020 15:07:43

US3672187

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:10

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:57
Amendment Manager: User entered '36.57439'	System	17 Sep 2020 00:13:46
User entered '36.6'	System	21 Aug 2020 12:47:25
DataPoint set to visible.	System	19 Aug 2020 15:07:43

US3672187

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:10

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:57
User entered 'kg/m2'	System	21 Aug 2020 12:47:25
DataPoint set to visible.	System	19 Aug 2020 15:07:43

US3672187

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered missing code ND - Not Done.	(b) (4), (b) (6)	21 Aug 2020 12:47:25

US3672187

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 12:47:25

US3672187

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:10

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 12:47:25

US3672187

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 12:47:25

US3672187

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:10

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:57
User entered 'bpm'	System	21 Aug 2020 12:47:25

US3672187

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 12:47:25

US3672187

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:57
User entered 'breaths/min'	System	21 Aug 2020 12:47:25

US3672187

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 12:47:25

US3672187

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:10

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:57
User entered 'mmHg'	System	21 Aug 2020 12:47:25

US3672187

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 12:47:25

US3672187

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:10

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:57
User entered 'mmHg'	System	21 Aug 2020 12:47:25

US3672187

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:10

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:57

US3672187

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:10

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:57

US3672187

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:22:10

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 12:47:35

US3672187

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:22:10

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered '19 Aug 2020'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 12:47:35

US3672187

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 12:48:25

US3672187

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 12:48:25

US3672187

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:22:10

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)	30 Apr 2021 18:03:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 12:48:25

US3672187

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:22:10

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)	30 Apr 2021 18:03:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 12:48:25

US3672187

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 12:48:25

US3672187

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:22:10

[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)	30 Apr 2021 18:03:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 12:48:25

US3672187

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:22:10

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)	30 Apr 2021 18:03:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 12:48:25

US3672187

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:22:10

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)	30 Apr 2021 18:03:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 12:48:25

US3672187

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:22:10

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)	30 Apr 2021 18:03:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 12:48:25

US3672187

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:22:10

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)	30 Apr 2021 18:03:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 12:48:25

US3672187

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:22:10

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)	30 Apr 2021 18:03:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 12:48:25

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Folder: Screening

Form: Risk of Exposure

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Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 12:48:25

US3672187

Folder: Screening

Form: Risk of Exposure

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 12:48:25

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:22:10

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 12:48:25

US3672187

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 12:48:25

US3672187

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:22:10

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)	30 Apr 2021 18:03:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 12:48:25

US3672187

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:22:10

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)	30 Apr 2021 18:03:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 12:48:25

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:22:10

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)	30 Apr 2021 18:03:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 12:48:25

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered 'I'	(b) (4), (b) (6)	21 Aug 2020 12:48:25

US3672187

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:22:10

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 12:48:25

US3672187

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:22:10

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:57
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 12:48:25

US3672187

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:22:10

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 15:07:51

US3672187

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered '19 Aug 2020'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 15:07:51

US3672187

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:22:10

[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 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 15:07:51

US3672187

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:22:10

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User entered 'VISIT1'	System	19 Aug 2020 15:07:51

US3672187

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered '19 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 14:44:44

US3672187

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:22:10

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 05:32:05
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 05:32:05
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	19 Aug 2020 14:44:44
User entered '186989' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 14:44:44

US3672187

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 14:44:44

US3672187

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:22:10

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 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered 'No (N)'	Patty Howenstine (b) (4)	19 Aug 2020 14:34:57

US3672187

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:22:10

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 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered 'No (N)'	Patty Howenstine (b) (4)	19 Aug 2020 14:34:57

US3672187

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered 'No (N)'	(b) (4) Patty Howenstine (b) (4)	19 Aug 2020 14:34:57

US3672187

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered 'No (N)'	(b) (4) Patty Howenstine (b) (4)	19 Aug 2020 14:34:57

US3672187

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:22:10

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered 'No (N)'	(b) (4) Patty Howenstine (b) (4)	19 Aug 2020 14:34:57

US3672187

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:35:40
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 01:29:39

US3672187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:22:10

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 12:49:40

US3672187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:22:10

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 12:49:40

US3672187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:22:10

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 12:49:40

US3672187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:22:10

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 12:49:40

US3672187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:10

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	21 Aug 2020 12:49:40

US3672187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 12:49:40

US3672187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered '19 Aug 2020'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 12:49:40

US3672187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered '10:32'	(b) (4), (b) (6)	21 Aug 2020 12:49:40

US3672187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User entered '19 Aug 2020 10:32'	System	21 Aug 2020 12:49:40

US3672187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered '98.0' F	(b) (4), (b) (6)	21 Aug 2020 12:49:40

US3672187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 12:49:40

US3672187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:10

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 12:49:40

US3672187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered '53'	(b) (4), (b) (6)	21 Aug 2020 12:49:40

US3672187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:10

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User entered 'bpm'	System	21 Aug 2020 12:49:40

US3672187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered '16'	(b) (4), (b) (6)	21 Aug 2020 12:49:40

US3672187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User entered 'breaths/min'	System	21 Aug 2020 12:49:40

US3672187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:10

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	21 Aug 2020 13:26:35
Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS per investigator' (Site from System).	(b) (4), (b) (6)	21 Aug 2020 12:50:03
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	21 Aug 2020 12:49:40
User entered '157'	(b) (4), (b) (6)	21 Aug 2020 12:49:40

US3672187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:10

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User entered 'mmHg'	System	21 Aug 2020 12:49:40

US3672187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:10

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered '97'	(b) (4), (b) (6)	21 Aug 2020 12:49:40

US3672187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:10

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User entered 'mmHg'	System	21 Aug 2020 12:49:40

US3672187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:22:10

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered missing code ND - Not Done.	(b) (4), (b) (6)	21 Aug 2020 12:49:40

US3672187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:22:10

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 12:49:40

US3672187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:10

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	21 Aug 2020 12:49:40

US3672187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 12:49:40

US3672187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered '19 Aug 2020'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 12:49:40

US3672187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered '11:42'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 12:49:40

US3672187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User entered '19 Aug 2020 11:42'	System	21 Aug 2020 12:49:40

US3672187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered '97.8' F	(b) (4), (b) (6)	21 Aug 2020 12:49:40

US3672187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 12:49:40

US3672187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:10

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 12:49:40

US3672187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered '50'	(b) (4), (b) (6)	21 Aug 2020 12:49:40

US3672187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:10

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User entered 'bpm'	System	21 Aug 2020 12:49:40

US3672187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered '16'	(b) (4), (b) (6)	21 Aug 2020 12:49:40

US3672187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User entered 'breaths/min'	System	21 Aug 2020 12:49:40

US3672187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:10

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	21 Aug 2020 13:26:46
Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS per investigator' (Site from System).	(b) (4), (b) (6)	21 Aug 2020 12:50:09
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	21 Aug 2020 12:49:40
User entered '156'	(b) (4), (b) (6)	21 Aug 2020 12:49:40

US3672187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:10

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User entered 'mmHg'	System	21 Aug 2020 12:49:40

US3672187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered '89'	(b) (4), (b) (6)	21 Aug 2020 12:49:40

US3672187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:10

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User entered 'mmHg'	System	21 Aug 2020 12:49:40

US3672187

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:22:10

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 12:50:15

US3672187

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:22:10

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered '19 Aug 2020'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 12:50:15

US3672187

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:22:10

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 15:08:46

US3672187

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:22:10

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 15:08:46

US3672187

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:22:10

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 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 15:08:46

US3672187

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:22:10

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User entered 'MRNA-1273 OR PLACEBO'	System	19 Aug 2020 15:08:46

US3672187

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered '19 Aug 2020'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 15:08:46

US3672187

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered '11:06'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 15:08:46

US3672187

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User entered '19 Aug 2020 11:06'	System	19 Aug 2020 15:08:46

US3672187

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 15:08:46

US3672187

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:22:10

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User entered 'ONCE'	System	19 Aug 2020 15:08:46

US3672187

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User entered 'INTRAMUSCULAR'	System	19 Aug 2020 15:08:46

US3672187

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:22:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 12:50:32

US3672187

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:22:10

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered '19 Aug 2020'	(b) (4), (b) (6)	21 Aug 2020 12:50:32

US3672187

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered '10:43'	(b) (4), (b) (6)	21 Aug 2020 12:50:32

US3672187

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User entered '19 Aug 2020 10:43'	System	21 Aug 2020 12:50:32

US3672187

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:22:10

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered '19 Aug 2020'	(b) (4), (b) (6)	21 Aug 2020 12:50:43

US3672187

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:22:10

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	21 Aug 2020 12:50:43

US3672187

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:22:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 12:50:43

US3672187

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:22:10

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered '10:20'	(b) (4), (b) (6)	21 Aug 2020 12:50:43

US3672187

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User entered '19 Aug 2020 10:20'	System	21 Aug 2020 12:50:43

US3672187

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:22:10

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	21 Aug 2020 12:50:43

US3672187

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:22:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 12:50:43

US3672187

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:22:10

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 12:50:43

US3672187

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User entered empty.	System	21 Aug 2020 12:50:43

US3672187

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 12:50:48

US3672187

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:22:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User entered 'I'	System	21 Aug 2020 12:50:48

US3672187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
Data entry locked.	System	19 Aug 2020 15:08:46
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Aug 2020 15:08:46

US3672187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:22:10

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-19T11:39:28', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '211d7f77-4b68-4e2a-bdff-bce83acafd9a'	System	19 Aug 2020 15:40:05
User entered 'Yes (Y)'	System	19 Aug 2020 15:40:05

US3672187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:22:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-19T11:39:45', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '211d7f77-4b68-4e2a-bdff-bce83acafd9a' User entered '97.8'	System	19 Aug 2020 15:40:05
	System	19 Aug 2020 15:40:05

US3672187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-19T11:39:52', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '211d7f77-4b68-4e2a-bdff-bce83acafd9a'	System	19 Aug 2020 15:40:05
User entered 'No (N)'	System	19 Aug 2020 15:40:05

US3672187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:22:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-19T11:40:00', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '211d7f77-4b68-4e2a-bdff-bce83acafd9a'	System	19 Aug 2020 15:40:05
User entered '19 Aug 2020 11:40'	System	19 Aug 2020 15:40:05

US3672187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:22:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
User entered '19 Aug 2020 11:26'	System	19 Aug 2020 15:08:46

US3672187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:22:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
User entered '19 Aug 2020 13:56'	System	19 Aug 2020 15:08:46

US3672187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
Data entry locked.	System	19 Aug 2020 15:08:46
User entered 'Day 1, after vaccination (at home)'	System	19 Aug 2020 15:08:46

US3672187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:22:10

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-19T21:32:12', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '1d5cea9f-0c34-462e-8f3b-00db98fe894e'	System	20 Aug 2020 01:32:42
User entered 'Yes (Y)'	System	20 Aug 2020 01:32:42

US3672187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:22:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-19T21:32:24', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '1d5cea9f-0c34-462e-8f3b-00db98fe894e'	System	20 Aug 2020 01:32:42
User entered '97.8'	System	20 Aug 2020 01:32:42

US3672187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-19T21:32:30', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '1d5cea9f-0c34-462e-8f3b-00db98fe894e'	System	20 Aug 2020 01:32:42
User entered 'No (N)'	System	20 Aug 2020 01:32:42

US3672187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:22:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-19T21:32:37', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '1d5cea9f-0c34-462e-8f3b-00db98fe894e'	System	20 Aug 2020 01:32:42
User entered '19 Aug 2020 21:32'	System	20 Aug 2020 01:32:42

US3672187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:22:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
User entered '19 Aug 2020 14:51'	System	19 Aug 2020 15:08:46

US3672187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:22:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
User entered '20 Aug 2020 11:59'	System	19 Aug 2020 15:08:46

US3672187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
Data entry locked.	System	19 Aug 2020 15:08:46
User entered 'Day 2'	System	19 Aug 2020 15:08:46

US3672187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:22:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-20T21:12:10', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '67789e99-1839-4898-83a9-92304d3e03ae'	System	21 Aug 2020 01:12:33
User entered 'Yes (Y)'	System	21 Aug 2020 01:12:33

US3672187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:22:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-20T21:12:19', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '67789e99-1839-4898-83a9-92304d3e03ae' User entered '98.0'	System	21 Aug 2020 01:12:33
	System	21 Aug 2020 01:12:33

US3672187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-20T21:12:24', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '67789e99-1839-4898-83a9-92304d3e03ae'	System	21 Aug 2020 01:12:33
User entered 'No (N)'	System	21 Aug 2020 01:12:33

US3672187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:22:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-20T21:12:28', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '67789e99-1839-4898-83a9-92304d3e03ae'	System	21 Aug 2020 01:12:33
User entered '20 Aug 2020 21:12'	System	21 Aug 2020 01:12:33

US3672187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:22:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 15:08:46

US3672187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:22:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 15:08:46

US3672187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
Data entry locked.	System	19 Aug 2020 15:08:46
User entered 'Day 3'	System	19 Aug 2020 15:08:46

US3672187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:22:10

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-21T19:03:07', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '86bede97-37bf-4e17-8e79-47f4733955f5'	System	21 Aug 2020 23:03:26
User entered 'Yes (Y)'	System	21 Aug 2020 23:03:26

US3672187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:22:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-21T19:03:17', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '86bede97-37bf-4e17-8e79-47f4733955f5'	System	21 Aug 2020 23:03:26
User entered '97.6'	System	21 Aug 2020 23:03:26

US3672187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-21T19:03:21', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '86bede97-37bf-4e17-8e79-47f4733955f5'	System	21 Aug 2020 23:03:26
User entered 'No (N)'	System	21 Aug 2020 23:03:26

US3672187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:22:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-21T19:03:24', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '86bede97-37bf-4e17-8e79-47f4733955f5'	System	21 Aug 2020 23:03:26
User entered '21 Aug 2020 19:03'	System	21 Aug 2020 23:03:26

US3672187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:22:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 15:08:46

US3672187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:22:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 15:08:46

US3672187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
Data entry locked.	System	19 Aug 2020 15:08:46
User entered 'Day 4'	System	19 Aug 2020 15:08:46

US3672187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:22:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-22T19:14:09', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '80f45d82-c4e6-46c3-b1b3-4b3db67c73f9'	System	22 Aug 2020 23:14:37
User entered 'Yes (Y)'	System	22 Aug 2020 23:14:37

US3672187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:22:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-22T19:14:24', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '80f45d82-c4e6-46c3-b1b3-4b3db67c73f9'	System	22 Aug 2020 23:14:37
User entered '97.6'	System	22 Aug 2020 23:14:37

US3672187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-22T19:14:29', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '80f45d82-c4e6-46c3-b1b3-4b3db67c73f9'	System	22 Aug 2020 23:14:37
User entered 'No (N)'	System	22 Aug 2020 23:14:37

US3672187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:22:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-22T19:14:34', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '80f45d82-c4e6-46c3-b1b3-4b3db67c73f9'	System	22 Aug 2020 23:14:37
User entered '22 Aug 2020 19:14'	System	22 Aug 2020 23:14:37

US3672187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:22:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
User entered '22 Aug 2020 12:00'	System	19 Aug 2020 15:08:46

US3672187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:22:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
User entered '23 Aug 2020 11:59'	System	19 Aug 2020 15:08:46

US3672187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
Data entry locked.	System	19 Aug 2020 15:08:46
User entered 'Day 5'	System	19 Aug 2020 15:08:46

US3672187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:22:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30

US3672187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:22:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30

US3672187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30

US3672187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30

US3672187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:22:10

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30

US3672187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:22:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30

US3672187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:22:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
User entered '23 Aug 2020 12:00'	System	19 Aug 2020 15:08:46

US3672187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:22:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
User entered '24 Aug 2020 11:59'	System	19 Aug 2020 15:08:46

US3672187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
Data entry locked.	System	19 Aug 2020 15:08:46
User entered 'Day 6'	System	19 Aug 2020 15:08:46

US3672187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:22:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-24T19:18:18', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '46825a62-e10a-419e-a019-da41f57434aa'	System	24 Aug 2020 23:18:37
User entered 'Yes (Y)'	System	24 Aug 2020 23:18:37

US3672187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:22:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-24T19:18:25', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '46825a62-e10a-419e-a019-da41f57434aa'	System	24 Aug 2020 23:18:37
User entered '98.0'	System	24 Aug 2020 23:18:37

US3672187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-24T19:18:28', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '46825a62-e10a-419e-a019-da41f57434aa'	System	24 Aug 2020 23:18:37
User entered 'No (N)'	System	24 Aug 2020 23:18:37

US3672187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:22:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-24T19:18:32', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '46825a62-e10a-419e-a019-da41f57434aa'	System	24 Aug 2020 23:18:37
User entered '24 Aug 2020 19:18'	System	24 Aug 2020 23:18:37

US3672187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:22:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
User entered '24 Aug 2020 12:00'	System	19 Aug 2020 15:08:46

US3672187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:22:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
User entered '25 Aug 2020 11:59'	System	19 Aug 2020 15:08:46

US3672187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
Data entry locked.	System	19 Aug 2020 15:08:46
User entered 'Day 7'	System	19 Aug 2020 15:08:46

US3672187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:22:10

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-25T20:44:54', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '32e503c4-4dac-4231-a0df-0a9955375940'	System	26 Aug 2020 00:45:12
User entered 'Yes (Y)'	System	26 Aug 2020 00:45:12

US3672187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:22:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-25T20:45:02', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '32e503c4-4dac-4231-a0df-0a9955375940'	System	26 Aug 2020 00:45:12
User entered '97.8'	System	26 Aug 2020 00:45:12

US3672187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-25T20:45:05', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '32e503c4-4dac-4231-a0df-0a9955375940'	System	26 Aug 2020 00:45:12
User entered 'No (N)'	System	26 Aug 2020 00:45:12

US3672187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:22:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-25T20:45:09', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '32e503c4-4dac-4231-a0df-0a9955375940'	System	26 Aug 2020 00:45:12
User entered '25 Aug 2020 20:45'	System	26 Aug 2020 00:45:12

US3672187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:22:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
User entered '25 Aug 2020 12:00'	System	19 Aug 2020 15:08:46

US3672187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:22:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
User entered '26 Aug 2020 11:59'	System	19 Aug 2020 15:08:46

US3672187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
Data entry locked.	System	19 Aug 2020 15:08:46
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Aug 2020 15:08:46

US3672187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:22:10

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 06:14:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-19T11:40:36', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '4ae2e5e7-8e24-444b-b940-36df481f4990'	System	19 Aug 2020 15:41:28
User entered 'None (1)'	System	19 Aug 2020 15:41:28

US3672187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:22:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-19T11:40:43', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '4ae2e5e7-8e24-444b-b940-36df481f4990'	System	19 Aug 2020 15:41:28
User entered 'No (N)'	System	19 Aug 2020 15:41:28

US3672187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-19T11:41:19', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '4ae2e5e7-8e24-444b-b940-36df481f4990'	System	19 Aug 2020 15:41:28
User entered 'No (N)'	System	19 Aug 2020 15:41:28

US3672187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:22:10

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 06:14:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-19T11:41:04', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '4ae2e5e7-8e24-444b-b940-36df481f4990'	System	19 Aug 2020 15:41:28
User entered 'None (1)'	System	19 Aug 2020 15:41:28

US3672187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:22:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-19T11:41:24', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '4ae2e5e7-8e24-444b-b940-36df481f4990'	System	19 Aug 2020 15:41:28
User entered '19 Aug 2020 11:41'	System	19 Aug 2020 15:41:28

US3672187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:22:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
User entered '19 Aug 2020 11:26'	System	19 Aug 2020 15:08:46

US3672187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:22:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
User entered '19 Aug 2020 13:56'	System	19 Aug 2020 15:08:46

US3672187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
Data entry locked.	System	19 Aug 2020 15:08:46
User entered 'Day 1, after vaccination (at home)'	System	19 Aug 2020 15:08:46

US3672187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:22:10

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 06:14:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-19T21:32:47', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '35ed6045-c0e1-4043-9a21-55f578d84275'	System	20 Aug 2020 01:33:08
User entered 'None (1)'	System	20 Aug 2020 01:33:08

US3672187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:22:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-19T21:32:52', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '35ed6045-c0e1-4043-9a21-55f578d84275'	System	20 Aug 2020 01:33:08
User entered 'No (N)'	System	20 Aug 2020 01:33:08

US3672187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-19T21:32:56', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '35ed6045-c0e1-4043-9a21-55f578d84275'	System	20 Aug 2020 01:33:08
User entered 'No (N)'	System	20 Aug 2020 01:33:08

US3672187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:22:10

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 06:14:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-19T21:33:00', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '35ed6045-c0e1-4043-9a21-55f578d84275'	System	20 Aug 2020 01:33:08
User entered 'None (1)'	System	20 Aug 2020 01:33:08

US3672187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:22:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-19T21:33:07', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '35ed6045-c0e1-4043-9a21-55f578d84275'	System	20 Aug 2020 01:33:08
User entered '19 Aug 2020 21:33'	System	20 Aug 2020 01:33:08

US3672187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:22:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
User entered '19 Aug 2020 14:51'	System	19 Aug 2020 15:08:46

US3672187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:22:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
User entered '20 Aug 2020 11:59'	System	19 Aug 2020 15:08:46

US3672187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
Data entry locked.	System	19 Aug 2020 15:08:46
User entered 'Day 2'	System	19 Aug 2020 15:08:46

US3672187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:22:10

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 06:14:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-20T21:12:34', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '20655d18-d8fc-4877-9045-f4ff23c30fd2'	System	21 Aug 2020 01:12:56
User entered 'None (1)'	System	21 Aug 2020 01:12:56

US3672187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:22:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-20T21:12:38', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '20655d18-d8fc-4877-9045-f4ff23c30fd2'	System	21 Aug 2020 01:12:56
User entered 'No (N)'	System	21 Aug 2020 01:12:56

US3672187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-20T21:12:42', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '20655d18-d8fc-4877-9045-f4ff23c30fd2'	System	21 Aug 2020 01:12:56
User entered 'No (N)'	System	21 Aug 2020 01:12:56

US3672187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:22:10

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 06:14:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-20T21:12:45', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '20655d18-d8fc-4877-9045-f4ff23c30fd2'	System	21 Aug 2020 01:12:56
User entered 'None (1)'	System	21 Aug 2020 01:12:56

US3672187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:22:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-20T21:12:52', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '20655d18-d8fc-4877-9045-f4ff23c30fd2'	System	21 Aug 2020 01:12:56
User entered '20 Aug 2020 21:12'	System	21 Aug 2020 01:12:56

US3672187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:22:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 15:08:46

US3672187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:22:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 15:08:46

US3672187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
Data entry locked.	System	19 Aug 2020 15:08:46
User entered 'Day 3'	System	19 Aug 2020 15:08:46

US3672187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:22:10

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 06:14:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-21T19:03:29', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '457a1f3c-a70e-46ad-952c-1a17e82a2d7a'	System	21 Aug 2020 23:03:43
User entered 'None (1)'	System	21 Aug 2020 23:03:43

US3672187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-21T19:03:32', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '457a1f3c-a70e-46ad-952c-1a17e82a2d7a'	System	21 Aug 2020 23:03:43
User entered 'No (N)'	System	21 Aug 2020 23:03:43

US3672187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-21T19:03:35', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '457a1f3c-a70e-46ad-952c-1a17e82a2d7a'	System	21 Aug 2020 23:03:43
User entered 'No (N)'	System	21 Aug 2020 23:03:43

US3672187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:22:10

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 06:14:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-21T19:03:38', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '457a1f3c-a70e-46ad-952c-1a17e82a2d7a'	System	21 Aug 2020 23:03:43
User entered 'None (1)'	System	21 Aug 2020 23:03:43

US3672187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:22:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-21T19:03:41', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '457a1f3c-a70e-46ad-952c-1a17e82a2d7a'	System	21 Aug 2020 23:03:43
User entered '21 Aug 2020 19:03'	System	21 Aug 2020 23:03:43

US3672187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:22:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 15:08:46

US3672187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:22:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 15:08:46

US3672187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
Data entry locked.	System	19 Aug 2020 15:08:46
User entered 'Day 4'	System	19 Aug 2020 15:08:46

US3672187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:22:10

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 06:14:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-22T19:14:40', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: 'bbe4250d-d9ee-44bf-ab3f-461224b1e1d8'	System	22 Aug 2020 23:15:05
User entered 'None (1)'	System	22 Aug 2020 23:15:05

US3672187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:22:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-22T19:14:44', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: 'bbe4250d-d9ee-44bf-ab3f-461224b1e1d8'	System	22 Aug 2020 23:15:05
User entered 'No (N)'	System	22 Aug 2020 23:15:05

US3672187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-22T19:14:48', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: 'bbe4250d-d9ee-44bf-ab3f-461224b1e1d8'	System	22 Aug 2020 23:15:05
User entered 'No (N)'	System	22 Aug 2020 23:15:05

US3672187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:22:10

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 06:14:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-22T19:14:52', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: 'bbe4250d-d9ee-44bf-ab3f-461224b1e1d8'	System	22 Aug 2020 23:15:05
User entered 'None (1)'	System	22 Aug 2020 23:15:05

US3672187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:22:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-22T19:14:59', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: 'bbe4250d-d9ee-44bf-ab3f-461224b1e1d8'	System	22 Aug 2020 23:15:05
User entered '22 Aug 2020 19:14'	System	22 Aug 2020 23:15:05

US3672187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:22:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
User entered '22 Aug 2020 12:00'	System	19 Aug 2020 15:08:46

US3672187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:22:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
User entered '23 Aug 2020 11:59'	System	19 Aug 2020 15:08:46

US3672187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
Data entry locked.	System	19 Aug 2020 15:08:46
User entered 'Day 5'	System	19 Aug 2020 15:08:46

US3672187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:22:10

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 06:14:30

US3672187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:22:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30

US3672187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:22:10

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30

US3672187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30

US3672187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:22:10

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30

US3672187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:22:10

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 06:14:30

US3672187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:22:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30

US3672187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:22:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
User entered '23 Aug 2020 12:00'	System	19 Aug 2020 15:08:46

US3672187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:22:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
User entered '24 Aug 2020 11:59'	System	19 Aug 2020 15:08:46

US3672187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
Data entry locked.	System	19 Aug 2020 15:08:46
User entered 'Day 6'	System	19 Aug 2020 15:08:46

US3672187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:22:10

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 06:14:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-24T19:18:36', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: 'f403e59f-c960-4e5c-b892-0467d07ff7b5'	System	24 Aug 2020 23:18:48
User entered 'None (1)'	System	24 Aug 2020 23:18:48

US3672187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:22:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-24T19:18:38', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: 'f403e59f-c960-4e5c-b892-0467d07ff7b5'	System	24 Aug 2020 23:18:48
User entered 'No (N)'	System	24 Aug 2020 23:18:48

US3672187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-24T19:18:41', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: 'f403e59f-c960-4e5c-b892-0467d07ff7b5'	System	24 Aug 2020 23:18:48
User entered 'No (N)'	System	24 Aug 2020 23:18:48

US3672187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:22:10

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 06:14:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-24T19:18:43', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: 'f403e59f-c960-4e5c-b892-0467d07ff7b5'	System	24 Aug 2020 23:18:48
User entered 'None (1)'	System	24 Aug 2020 23:18:48

US3672187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:22:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-24T19:18:46', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: 'f403e59f-c960-4e5c-b892-0467d07ff7b5'	System	24 Aug 2020 23:18:48
User entered '24 Aug 2020 19:18'	System	24 Aug 2020 23:18:48

US3672187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:22:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
User entered '24 Aug 2020 12:00'	System	19 Aug 2020 15:08:46

US3672187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:22:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
User entered '25 Aug 2020 11:59'	System	19 Aug 2020 15:08:46

US3672187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
Data entry locked.	System	19 Aug 2020 15:08:46
User entered 'Day 7'	System	19 Aug 2020 15:08:46

US3672187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:22:10

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 06:14:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-25T20:45:13', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: 'ecdd99d7-198a-4f61-95be-e3404b3c5af2'	System	26 Aug 2020 00:45:28
User entered 'None (1)'	System	26 Aug 2020 00:45:28

US3672187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-25T20:45:15', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: 'ecdd99d7-198a-4f61-95be-e3404b3c5af2'	System	26 Aug 2020 00:45:28
User entered 'No (N)'	System	26 Aug 2020 00:45:28

US3672187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-25T20:45:18', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: 'ecdd99d7-198a-4f61-95be-e3404b3c5af2'	System	26 Aug 2020 00:45:28
User entered 'No (N)'	System	26 Aug 2020 00:45:28

US3672187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:22:10

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 06:14:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-25T20:45:20', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: 'ecdd99d7-198a-4f61-95be-e3404b3c5af2'	System	26 Aug 2020 00:45:28
User entered 'None (1)'	System	26 Aug 2020 00:45:28

US3672187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:22:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-25T20:45:24', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: 'ecdd99d7-198a-4f61-95be-e3404b3c5af2'	System	26 Aug 2020 00:45:28
User entered '25 Aug 2020 20:45'	System	26 Aug 2020 00:45:28

US3672187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:22:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
User entered '25 Aug 2020 12:00'	System	19 Aug 2020 15:08:46

US3672187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:22:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
User entered '26 Aug 2020 11:59'	System	19 Aug 2020 15:08:46

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:27
Data entry locked.	System	19 Aug 2020 15:08:46
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Aug 2020 15:08:46

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:22:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-19T11:41:30', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '54c14a0a-21b1-40ae-b14c-0cd4a3b3c79e'	System	19 Aug 2020 15:42:00
User entered 'None (0)'	System	19 Aug 2020 15:42:00

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:22:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-19T11:41:34', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '54c14a0a-21b1-40ae-b14c-0cd4a3b3c79e'	System	19 Aug 2020 15:42:00
User entered 'None (0)'	System	19 Aug 2020 15:42:00

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:22:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-19T11:41:37', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '54c14a0a-21b1-40ae-b14c-0cd4a3b3c79e'	System	19 Aug 2020 15:42:00
User entered 'None (0)'	System	19 Aug 2020 15:42:00

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:22:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-19T11:41:40', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '54c14a0a-21b1-40ae-b14c-0cd4a3b3c79e'	System	19 Aug 2020 15:42:00
User entered 'None (0)'	System	19 Aug 2020 15:42:00

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:22:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-19T11:41:42', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '54c14a0a-21b1-40ae-b14c-0cd4a3b3c79e'	System	19 Aug 2020 15:42:00
User entered 'None (0)'	System	19 Aug 2020 15:42:00

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:22:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-19T11:41:45', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '54c14a0a-21b1-40ae-b14c-0cd4a3b3c79e'	System	19 Aug 2020 15:42:00
User entered 'None (0)'	System	19 Aug 2020 15:42:00

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:22:10

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 06:14:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-19T11:41:51', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '54c14a0a-21b1-40ae-b14c-0cd4a3b3c79e'	System	19 Aug 2020 15:42:00
User entered 'No (N)'	System	19 Aug 2020 15:42:00

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:22:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-19T11:41:56', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '54c14a0a-21b1-40ae-b14c-0cd4a3b3c79e'	System	19 Aug 2020 15:42:00
User entered '19 Aug 2020 11:41'	System	19 Aug 2020 15:42:00

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:22:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:27
User entered '19 Aug 2020 11:26'	System	19 Aug 2020 15:08:46

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:22:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:27
User entered '19 Aug 2020 13:56'	System	19 Aug 2020 15:08:46

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:27
Data entry locked.	System	19 Aug 2020 15:08:46
User entered 'Day 1, after vaccination (at home)'	System	19 Aug 2020 15:08:46

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:22:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-19T21:33:15', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '29607d90-9ed1-4a0c-aada-fd04dca88033'	System	20 Aug 2020 01:33:45
User entered 'None (0)'	System	20 Aug 2020 01:33:45

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:22:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-19T21:33:19', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '29607d90-9ed1-4a0c-aada-fd04dca88033'	System	20 Aug 2020 01:33:45
User entered 'None (0)'	System	20 Aug 2020 01:33:45

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:22:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-19T21:33:22', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '29607d90-9ed1-4a0c-aada-fd04dca88033'	System	20 Aug 2020 01:33:45
User entered 'None (0)'	System	20 Aug 2020 01:33:45

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:22:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-19T21:33:24', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '29607d90-9ed1-4a0c-aada-fd04dca88033'	System	20 Aug 2020 01:33:45
User entered 'None (0)'	System	20 Aug 2020 01:33:45

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:22:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-19T21:33:27', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '29607d90-9ed1-4a0c-aada-fd04dca88033'	System	20 Aug 2020 01:33:45
User entered 'None (0)'	System	20 Aug 2020 01:33:45

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:22:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-19T21:33:29', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '29607d90-9ed1-4a0c-aada-fd04dca88033'	System	20 Aug 2020 01:33:45
User entered 'None (0)'	System	20 Aug 2020 01:33:45

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:22:10

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 06:14:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-19T21:33:36', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '29607d90-9ed1-4a0c-aada-fd04dca88033'	System	20 Aug 2020 01:33:45
User entered 'No (N)'	System	20 Aug 2020 01:33:45

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:22:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-19T21:33:41', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '29607d90-9ed1-4a0c-aada-fd04dca88033'	System	20 Aug 2020 01:33:45
User entered '19 Aug 2020 21:33'	System	20 Aug 2020 01:33:45

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:22:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:27
User entered '19 Aug 2020 14:51'	System	19 Aug 2020 15:08:46

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:22:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:27
User entered '20 Aug 2020 11:59'	System	19 Aug 2020 15:08:46

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:27
Data entry locked.	System	19 Aug 2020 15:08:46
User entered 'Day 2'	System	19 Aug 2020 15:08:46

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:22:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-20T21:12:57', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '587ea8f3-15c5-42f4-b1a6-ea19d86ef8ca'	System	21 Aug 2020 01:13:24
User entered 'None (0)'	System	21 Aug 2020 01:13:24

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:22:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-20T21:13:00', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '587ea8f3-15c5-42f4-b1a6-ea19d86ef8ca'	System	21 Aug 2020 01:13:24
User entered 'None (0)'	System	21 Aug 2020 01:13:24

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:22:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-20T21:13:02', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '587ea8f3-15c5-42f4-b1a6-ea19d86ef8ca'	System	21 Aug 2020 01:13:24
User entered 'None (0)'	System	21 Aug 2020 01:13:24

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:22:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-20T21:13:05', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '587ea8f3-15c5-42f4-b1a6-ea19d86ef8ca' User entered 'None (0)'	System	21 Aug 2020 01:13:24
	System	21 Aug 2020 01:13:24

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:22:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-20T21:13:07', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '587ea8f3-15c5-42f4-b1a6-ea19d86ef8ca'	System	21 Aug 2020 01:13:24
User entered 'None (0)'	System	21 Aug 2020 01:13:24

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:22:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-20T21:13:09', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '587ea8f3-15c5-42f4-b1a6-ea19d86ef8ca'	System	21 Aug 2020 01:13:24
User entered 'None (0)'	System	21 Aug 2020 01:13:24

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:22:10

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 06:14:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-20T21:13:14', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '587ea8f3-15c5-42f4-b1a6-ea19d86ef8ca'	System	21 Aug 2020 01:13:24
User entered 'No (N)'	System	21 Aug 2020 01:13:24

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:22:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-20T21:13:21', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '587ea8f3-15c5-42f4-b1a6-ea19d86ef8ca'	System	21 Aug 2020 01:13:24
User entered '20 Aug 2020 21:13'	System	21 Aug 2020 01:13:24

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:22:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:27
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 15:08:46

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:22:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:27
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 15:08:46

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:27
Data entry locked.	System	19 Aug 2020 15:08:46
User entered 'Day 3'	System	19 Aug 2020 15:08:46

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:22:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-21T19:03:46', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '5fc228e7-dd40-4244-bbca-c7e1dcb0ae76'	System	21 Aug 2020 23:04:06
User entered 'None (0)'	System	21 Aug 2020 23:04:06

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:22:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-21T19:03:48', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '5fc228e7-dd40-4244-bbca-c7e1dcb0ae76'	System	21 Aug 2020 23:04:06
User entered 'None (0)'	System	21 Aug 2020 23:04:06

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:22:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-21T19:03:50', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '5fc228e7-dd40-4244-bbca-c7e1dcb0ae76'	System	21 Aug 2020 23:04:06
User entered 'None (0)'	System	21 Aug 2020 23:04:06

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:22:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-21T19:03:52', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '5fc228e7-dd40-4244-bbca-c7e1dcb0ae76'	System	21 Aug 2020 23:04:06
User entered 'None (0)'	System	21 Aug 2020 23:04:06

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:22:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-21T19:03:54', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '5fc228e7-dd40-4244-bbca-c7e1dcb0ae76'	System	21 Aug 2020 23:04:06
User entered 'None (0)'	System	21 Aug 2020 23:04:06

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:22:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-21T19:03:56', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '5fc228e7-dd40-4244-bbca-c7e1dcb0ae76'	System	21 Aug 2020 23:04:06
User entered 'None (0)'	System	21 Aug 2020 23:04:06

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:22:10

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 06:14:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-21T19:03:59', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '5fc228e7-dd40-4244-bbca-c7e1dcb0ae76'	System	21 Aug 2020 23:04:06
User entered 'No (N)'	System	21 Aug 2020 23:04:06

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:22:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-21T19:04:03', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '5fc228e7-dd40-4244-bbca-c7e1dcb0ae76'	System	21 Aug 2020 23:04:06
User entered '21 Aug 2020 19:04'	System	21 Aug 2020 23:04:06

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:22:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:27
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 15:08:46

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:22:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:27
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 15:08:46

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:27
Data entry locked.	System	19 Aug 2020 15:08:46
User entered 'Day 4'	System	19 Aug 2020 15:08:46

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:22:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-22T19:15:08', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: 'b955186f-91c2-4339-acde-ae1c6d6e3b10'	System	22 Aug 2020 23:15:35
User entered 'None (0)'	System	22 Aug 2020 23:15:35

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:22:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-22T19:15:11', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: 'b955186f-91c2-4339-acde-ae1c6d6e3b10'	System	22 Aug 2020 23:15:35
User entered 'None (0)'	System	22 Aug 2020 23:15:35

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:22:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-22T19:15:13', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: 'b955186f-91c2-4339-acde-ae1c6d6e3b10'	System	22 Aug 2020 23:15:35
User entered 'None (0)'	System	22 Aug 2020 23:15:35

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:22:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-22T19:15:16', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: 'b955186f-91c2-4339-acde-ae1c6d6e3b10'	System	22 Aug 2020 23:15:35
User entered 'None (0)'	System	22 Aug 2020 23:15:35

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:22:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-22T19:15:19', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: 'b955186f-91c2-4339-acde-ae1c6d6e3b10'	System	22 Aug 2020 23:15:35
User entered 'None (0)'	System	22 Aug 2020 23:15:35

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:22:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-22T19:15:21', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: 'b955186f-91c2-4339-acde-ae1c6d6e3b10'	System	22 Aug 2020 23:15:35
User entered 'None (0)'	System	22 Aug 2020 23:15:35

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:22:10

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 06:14:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-22T19:15:25', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: 'b955186f-91c2-4339-acde-ae1c6d6e3b10'	System	22 Aug 2020 23:15:35
User entered 'No (N)'	System	22 Aug 2020 23:15:35

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:22:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-22T19:15:31', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: 'b955186f-91c2-4339-acde-ae1c6d6e3b10'	System	22 Aug 2020 23:15:35
User entered '22 Aug 2020 19:15'	System	22 Aug 2020 23:15:35

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:22:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:27
User entered '22 Aug 2020 12:00'	System	19 Aug 2020 15:08:46

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:22:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:27
User entered '23 Aug 2020 11:59'	System	19 Aug 2020 15:08:46

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:27
Data entry locked.	System	19 Aug 2020 15:08:46
User entered 'Day 5'	System	19 Aug 2020 15:08:46

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:22:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:27

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:22:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:27

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:22:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:27

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:22:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:27

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:22:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:27

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:22:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:27

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:22:10

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 06:14:27

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:22:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:27

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:22:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:27
User entered '23 Aug 2020 12:00'	System	19 Aug 2020 15:08:46

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:22:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:27
User entered '24 Aug 2020 11:59'	System	19 Aug 2020 15:08:46

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:27
Data entry locked.	System	19 Aug 2020 15:08:46
User entered 'Day 6'	System	19 Aug 2020 15:08:46

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:22:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-24T19:18:50', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: 'd76385a1-5e73-4624-9e7e-23bfd464d2a9'	System	24 Aug 2020 23:19:11
User entered 'None (0)'	System	24 Aug 2020 23:19:11

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:22:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-24T19:18:53', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: 'd76385a1-5e73-4624-9e7e-23bfd464d2a9'	System	24 Aug 2020 23:19:11
User entered 'None (0)'	System	24 Aug 2020 23:19:11

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:22:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-24T19:18:54', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: 'd76385a1-5e73-4624-9e7e-23bfd464d2a9'	System	24 Aug 2020 23:19:11
User entered 'None (0)'	System	24 Aug 2020 23:19:11

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:22:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-24T19:18:56', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: 'd76385a1-5e73-4624-9e7e-23bfd464d2a9'	System	24 Aug 2020 23:19:11
User entered 'None (0)'	System	24 Aug 2020 23:19:11

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:22:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-24T19:18:58', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: 'd76385a1-5e73-4624-9e7e-23bfd464d2a9'	System	24 Aug 2020 23:19:11
User entered 'None (0)'	System	24 Aug 2020 23:19:11

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:22:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-24T19:19:01', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: 'd76385a1-5e73-4624-9e7e-23bfd464d2a9'	System	24 Aug 2020 23:19:11
User entered 'None (0)'	System	24 Aug 2020 23:19:11

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:22:10

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 06:14:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-24T19:19:06', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: 'd76385a1-5e73-4624-9e7e-23bfd464d2a9'	System	24 Aug 2020 23:19:11
User entered 'No (N)'	System	24 Aug 2020 23:19:11

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:22:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-24T19:19:09', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: 'd76385a1-5e73-4624-9e7e-23bfd464d2a9'	System	24 Aug 2020 23:19:11
User entered '24 Aug 2020 19:19'	System	24 Aug 2020 23:19:11

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:22:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:27
User entered '24 Aug 2020 12:00'	System	19 Aug 2020 15:08:46

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:22:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:27
User entered '25 Aug 2020 11:59'	System	19 Aug 2020 15:08:46

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:27
Data entry locked.	System	19 Aug 2020 15:08:46
User entered 'Day 7'	System	19 Aug 2020 15:08:46

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:22:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-25T20:45:30', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: 'a48fa755-e8bf-4d90-970f-9510a2677ee9'	System	26 Aug 2020 00:45:51
User entered 'None (0)'	System	26 Aug 2020 00:45:51

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:22:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-25T20:45:32', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: 'a48fa755-e8bf-4d90-970f-9510a2677ee9'	System	26 Aug 2020 00:45:51
User entered 'None (0)'	System	26 Aug 2020 00:45:51

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:22:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-25T20:45:33', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: 'a48fa755-e8bf-4d90-970f-9510a2677ee9'	System	26 Aug 2020 00:45:51
User entered 'None (0)'	System	26 Aug 2020 00:45:51

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:22:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-25T20:45:35', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: 'a48fa755-e8bf-4d90-970f-9510a2677ee9'	System	26 Aug 2020 00:45:51
User entered 'None (0)'	System	26 Aug 2020 00:45:51

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:22:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-25T20:45:37', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: 'a48fa755-e8bf-4d90-970f-9510a2677ee9'	System	26 Aug 2020 00:45:51
User entered 'None (0)'	System	26 Aug 2020 00:45:51

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:22:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-25T20:45:39', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: 'a48fa755-e8bf-4d90-970f-9510a2677ee9'	System	26 Aug 2020 00:45:51
User entered 'None (0)'	System	26 Aug 2020 00:45:51

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:22:10

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 06:14:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-25T20:45:44', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: 'a48fa755-e8bf-4d90-970f-9510a2677ee9'	System	26 Aug 2020 00:45:51
User entered 'No (N)'	System	26 Aug 2020 00:45:51

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:22:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-08-25T20:45:48', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: 'a48fa755-e8bf-4d90-970f-9510a2677ee9'	System	26 Aug 2020 00:45:51
User entered '25 Aug 2020 20:45'	System	26 Aug 2020 00:45:51

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:22:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:27
User entered '25 Aug 2020 12:00'	System	19 Aug 2020 15:08:46

US3672187

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:22:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:27
User entered '26 Aug 2020 11:59'	System	19 Aug 2020 15:08:46

US3672187

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Aug 2020 19:17:07

US3672187

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered '27 Aug 2020'	(b) (4), (b) (6)	27 Aug 2020 19:17:07

US3672187

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	27 Aug 2020 19:17:07

US3672187

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:10

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 19:17:07

US3672187

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 19:17:12

US3672187

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User entered 'I'	System	27 Aug 2020 19:17:12

US3672187

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 14:21:16

US3672187

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:10

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User closed query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	15 Sep 2020 16:51:53
Query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'added pd due to subject being oow ' (Site from System).	(b) (4), (b) (6)	14 Sep 2020 14:21:25
User opened query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	14 Sep 2020 14:21:16
User entered '07 Sep 2020'	(b) (4), (b) (6)	14 Sep 2020 14:21:16

US3672187

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	14 Sep 2020 14:21:16

US3672187

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:10

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 14:21:16

US3672187

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 14:21:40

US3672187

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User entered 'I'	System	14 Sep 2020 14:21:40

US3672187

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 14:21:48

US3672187

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered '10 Sep 2020'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 14:21:48

US3672187

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	14 Sep 2020 14:21:48

US3672187

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:10

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 14:21:48

US3672187

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 14:21:52

US3672187

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User entered 'I'	System	14 Sep 2020 14:21:52

US3672187

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:22:10

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:21:47

US3672187

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered '21 Sep 2020'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:21:47

US3672187

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:22:10

[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 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:21:47

US3672187

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:22:10

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User entered 'VISIT2'	System	21 Sep 2020 20:21:47

US3672187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:10

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	21 Sep 2020 20:23:32

US3672187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:23:32

US3672187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered '21 Sep 2020'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:23:32

US3672187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered '10:20'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:23:32

US3672187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User entered '21 Sep 2020 10:20'	System	21 Sep 2020 20:23:32

US3672187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered '98' F	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:23:32

US3672187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:23:32

US3672187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:10

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:23:32

US3672187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered '67'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:23:32

US3672187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:10

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User entered 'bpm'	System	21 Sep 2020 20:23:32

US3672187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered '16'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:23:32

US3672187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User entered 'breaths/min'	System	21 Sep 2020 20:23:32

US3672187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered '158'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:23:32

US3672187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:10

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User entered 'mmHg'	System	21 Sep 2020 20:23:32

US3672187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:10

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4)	28 Oct 2020 04:35:10
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'CS and recorded as AE' (Site from System).	(b) (4), (b) (6)	27 Oct 2020 15:02:30
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		21 Sep 2020 20:23:32
User entered '120'	(b) (4), (b) (6)	21 Sep 2020 20:23:32

US3672187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:10

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User entered 'mmHg'	System	21 Sep 2020 20:23:32

US3672187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:10

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	21 Sep 2020 20:23:32

US3672187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:23:32

US3672187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:23:32

US3672187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:23:32

US3672187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User entered empty.	System	21 Sep 2020 20:23:32

US3672187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:23:32

US3672187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:23:32

US3672187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:10

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:23:32

US3672187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:23:32

US3672187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:10

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User entered empty.	System	21 Sep 2020 20:23:32

US3672187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:23:32

US3672187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User entered empty.	System	21 Sep 2020 20:23:32

US3672187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:10

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:23:32

US3672187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:10

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User entered empty.	System	21 Sep 2020 20:23:32

US3672187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:10

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:23:32

US3672187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:10

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User entered empty.	System	21 Sep 2020 20:23:32

US3672187

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:22:10

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:24:14

US3672187

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:22:10

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered '21 Sep 2020'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:24:14

US3672187

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:22:10

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:26:05

US3672187

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:22:10

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered 'Physician withheld dose due to Adverse Event (PHYSICIAN AE)'	(b) (4), (b) (6)	21 Sep 2020 20:26:05

US3672187

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:22:10

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 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered 'Elevated diastolic blood pressure (Grade 3).' reason for change: Data Entry Error	(b) (4)	21 Sep 2020 20:28:08
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 20:26:05

US3672187

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:22:10

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User entered empty.	System	21 Sep 2020 20:26:05

US3672187

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:26:05

US3672187

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:26:05

US3672187

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User entered empty.	System	21 Sep 2020 20:26:05

US3672187

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:26:05

US3672187

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User entered empty.	System	21 Sep 2020 20:26:05

US3672187

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User entered empty.	System	21 Sep 2020 20:26:05

US3672187

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:22:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:28:22

US3672187

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:22:10

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered '21 Sep 2020'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:28:22

US3672187

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered '10:47'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:28:22

US3672187

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User entered '21 Sep 2020 10:47'	System	21 Sep 2020 20:28:22

US3672187

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:22:10

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered '21 Sep 2020'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:28:38

US3672187

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:22:10

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	21 Sep 2020 20:28:38

US3672187

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:22:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:28:38

US3672187

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:22:10

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered '10:42'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:28:38

US3672187

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User entered '21 Sep 2020 10:42'	System	21 Sep 2020 20:28:38

US3672187

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:22:10

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	21 Sep 2020 20:28:38

US3672187

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:22:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:28:38

US3672187

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:22:10

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:28:38

US3672187

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User entered empty.	System	21 Sep 2020 20:28:38

US3672187

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:29:22

US3672187

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User entered 'I'	System	21 Sep 2020 20:29:22

US3672187

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:36:03

US3672187

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered '28 Sep 2020'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:36:03

US3672187

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:36:03

US3672187

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:10

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:36:03

US3672187

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:36:05

US3672187

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User entered 'I'	System	28 Sep 2020 18:36:05

US3672187

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 17:39:12

US3672187

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered '6 Oct 2020'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 17:39:12

US3672187

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 17:39:12

US3672187

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:10

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 17:39:12

US3672187

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 17:40:12

US3672187

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User entered 'I'	System	06 Oct 2020 17:40:12

US3672187

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:43:25

US3672187

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered '12 Oct 2020'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:43:25

US3672187

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:43:25

US3672187

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:10

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:43:25

US3672187

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:43:27

US3672187

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User entered 'I'	System	12 Oct 2020 15:43:27

US3672187

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:22:10

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 14:06:35

US3672187

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered '16 Oct 2020'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:06:35

US3672187

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:22:10

[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 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:06:35

US3672187

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:22:10

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User entered 'VISIT3'	System	16 Oct 2020 14:06:35

US3672187

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:07:04

US3672187

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered '16 Oct 2020'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:07:04

US3672187

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered '09:51'	(b) (4), (b) (6)	16 Oct 2020 14:07:04

US3672187

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User entered '16 Oct 2020 09:51'	System	16 Oct 2020 14:07:04

US3672187

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered '98.3' F	(b) (4), (b) (6)	16 Oct 2020 14:07:04

US3672187

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:07:04

US3672187

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:10

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:07:04

US3672187

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered '77'	(b) (4), (b) (6)	16 Oct 2020 14:07:04

US3672187

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:10

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User entered 'bpm'	System	16 Oct 2020 14:07:04

US3672187

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered '17'	(b) (4), (b) (6)	16 Oct 2020 14:07:04

US3672187

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User entered 'breaths/min'	System	16 Oct 2020 14:07:04

US3672187

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered '139'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:07:04

US3672187

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:10

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User entered 'mmHg'	System	16 Oct 2020 14:07:04

US3672187

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered '82'	(b) (4), (b) (6)	16 Oct 2020 14:07:04

US3672187

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:10

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User entered 'mmHg'	System	16 Oct 2020 14:07:04

US3672187

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:10

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58

US3672187

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:10

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58

US3672187

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:22:10

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:07:09

US3672187

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:22:10

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 14:07:09

US3672187

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:22:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:07:15

US3672187

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:22:10

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered '16 Oct 2020'	(b) (4), (b) (6)	16 Oct 2020 14:07:15

US3672187

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	
	System	16 Oct 2020 14:19:35
User entered '10:15' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Oct 2020 14:19:35
User opened query 'Data is required. Please provide.' (Site from System).		
	System	16 Oct 2020 14:07:15
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 14:07:15

US3672187

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User entered '16 Oct 2020 10:15'	System	16 Oct 2020 14:19:35
User entered empty.	System	16 Oct 2020 14:07:15

US3672187

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:01:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 14:07:20

US3672187

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User entered 'I'	System	16 Oct 2020 14:07:20

US3672187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
Data entry locked.	System	19 Aug 2020 15:08:46
User entered 'Day 64'	System	19 Aug 2020 15:08:46

US3672187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[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 06:14:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-10-19T09:47:33', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '6ed4b132-6a1f-4f50-be63-c800451d0629'	System	19 Oct 2020 13:47:44
User entered 'No (N)'	System	19 Oct 2020 13:47:44

US3672187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

Have you been exposed to someone with 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 06:14:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-10-19T09:47:37', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '6ed4b132-6a1f-4f50-be63-c800451d0629'	System	19 Oct 2020 13:47:44
User entered 'No (N)'	System	19 Oct 2020 13:47:44

US3672187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-10-19T09:47:40', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '6ed4b132-6a1f-4f50-be63-c800451d0629'	System	19 Oct 2020 13:47:44
User entered '19 Oct 2020 09:47:40'	System	19 Oct 2020 13:47:44

US3672187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
Data entry locked.	System	19 Aug 2020 15:08:46
User entered '19 Oct 2020 00:01'	System	19 Aug 2020 15:08:46

US3672187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
Data entry locked.	System	19 Aug 2020 15:08:46
User entered '23 Oct 2020 23:59'	System	19 Aug 2020 15:08:46

US3672187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
Data entry locked.	System	19 Aug 2020 15:08:46
User entered 'Day 71'	System	19 Aug 2020 15:08:46

US3672187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[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 06:14:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-10-26T15:51:32', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: 'fa112e1f-fcd2-42a3-80ad-d40259e10029'	System	26 Oct 2020 19:51:51
User entered 'No (N)'	System	26 Oct 2020 19:51:51

US3672187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

Have you been exposed to someone with 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 06:14:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-10-26T15:51:40', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: 'fa112e1f-fcd2-42a3-80ad-d40259e10029'	System	26 Oct 2020 19:51:51
User entered 'No (N)'	System	26 Oct 2020 19:51:51

US3672187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-10-26T15:51:47', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: 'fa112e1f-fcd2-42a3-80ad-d40259e10029' User entered '26 Oct 2020 15:51:47'	System	26 Oct 2020 19:51:51
	System	26 Oct 2020 19:51:51

US3672187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
Data entry locked.	System	19 Aug 2020 15:08:46
User entered '26 Oct 2020 00:01'	System	19 Aug 2020 15:08:46

US3672187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
Data entry locked.	System	19 Aug 2020 15:08:46
User entered '30 Oct 2020 23:59'	System	19 Aug 2020 15:08:46

US3672187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
Data entry locked.	System	19 Aug 2020 15:08:46
User entered 'Day 78'	System	19 Aug 2020 15:08:46

US3672187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[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 06:14:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-11-02T21:33:30', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '9f214bea-bd45-4f00-bd7e-3eb462278664'	System	03 Nov 2020 02:33:41
User entered 'No (N)'	System	03 Nov 2020 02:33:41

US3672187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

Have you been exposed to someone with 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 06:14:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-11-02T21:33:34', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '9f214bea-bd45-4f00-bd7e-3eb462278664'	System	03 Nov 2020 02:33:41
User entered 'No (N)'	System	03 Nov 2020 02:33:41

US3672187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-11-02T21:33:38', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '9f214bea-bd45-4f00-bd7e-3eb462278664'	System	03 Nov 2020 02:33:41
User entered '02 Nov 2020 21:33:38'	System	03 Nov 2020 02:33:41

US3672187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
Data entry locked.	System	19 Aug 2020 15:08:46
User entered '02 Nov 2020 00:01'	System	19 Aug 2020 15:08:46

US3672187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
Data entry locked.	System	19 Aug 2020 15:08:46
User entered '06 Nov 2020 23:59'	System	19 Aug 2020 15:08:46

US3672187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
Data entry locked.	System	19 Aug 2020 15:08:46
User entered 'Day 92'	System	19 Aug 2020 15:08:46

US3672187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[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 06:14:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-11-17T10:22:03', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '5385f992-c7fd-45ba-bd23-bbd9da44ad37'	System	17 Nov 2020 15:22:15
User entered 'No (N)'	System	17 Nov 2020 15:22:15

US3672187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

Have you been exposed to someone with 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 06:14:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-11-17T10:22:05', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '5385f992-c7fd-45ba-bd23-bbd9da44ad37'	System	17 Nov 2020 15:22:15
User entered 'No (N)'	System	17 Nov 2020 15:22:15

US3672187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-11-17T10:22:10', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '5385f992-c7fd-45ba-bd23-bbd9da44ad37'	System	17 Nov 2020 15:22:15
User entered '17 Nov 2020 10:22:10'	System	17 Nov 2020 15:22:15

US3672187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
Data entry locked.	System	19 Aug 2020 15:08:46
User entered '16 Nov 2020 00:01'	System	19 Aug 2020 15:08:46

US3672187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:14:30
Data entry locked.	System	19 Aug 2020 15:08:46
User entered '20 Nov 2020 23:59'	System	19 Aug 2020 15:08:46

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[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 (b9c41a5b25988163)', Time: '2020-11-20T14:24:38', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '27dd6f20-207d-48aa-9441-cdacd9d1a030'	System	20 Nov 2020 19:24:43
User entered 'No (N)'	System	20 Nov 2020 19:24:43

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

Have you been exposed to someone with 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 (b9c41a5b25988163)', Time: '2020-11-20T14:24:40', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '27dd6f20-207d-48aa-9441-cdacd9d1a030'	System	20 Nov 2020 19:24:43
User entered 'No (N)'	System	20 Nov 2020 19:24:43

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-11-20T14:24:44', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '27dd6f20-207d-48aa-9441-cdacd9d1a030'	System	20 Nov 2020 19:24:43
User entered '20 Nov 2020 14:24:44'	System	20 Nov 2020 19:24:43

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[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 (b9c41a5b25988163)', Time: '2020-11-27T17:55:26', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '9389cc04-6656-4450-a16e-07201ac785ca'	System	27 Nov 2020 22:55:40
User entered 'No (N)'	System	27 Nov 2020 22:55:40

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

Have you been exposed to someone with 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 (b9c41a5b25988163)', Time: '2020-11-27T17:55:31', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '9389cc04-6656-4450-a16e-07201ac785ca'	System	27 Nov 2020 22:55:40
User entered 'No (N)'	System	27 Nov 2020 22:55:40

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-11-27T17:55:41', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '9389cc04-6656-4450-a16e-07201ac785ca' User entered '27 Nov 2020 17:55:41'	System	27 Nov 2020 22:55:40
	System	27 Nov 2020 22:55:40

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[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 (b9c41a5b25988163)', Time: '2020-12-04T20:42:49', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '56b3bd0a-22dc-49ef-83b7-5bb7af3afa89'	System	05 Dec 2020 01:42:38
User entered 'No (N)'	System	05 Dec 2020 01:42:38

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

Have you been exposed to someone with 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 (b9c41a5b25988163)', Time: '2020-12-04T20:42:52', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '56b3bd0a-22dc-49ef-83b7-5bb7af3afa89'	System	05 Dec 2020 01:42:38
User entered 'No (N)'	System	05 Dec 2020 01:42:38

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-12-04T20:42:59', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '56b3bd0a-22dc-49ef-83b7-5bb7af3afa89'	System	05 Dec 2020 01:42:38
User entered '04 Dec 2020 20:42:59'	System	05 Dec 2020 01:42:38

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[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 (b9c41a5b25988163)', Time: '2020-12-12T21:32:26', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '7fb51eca-1d13-4c21-bdf0-9fda223147fd'	System	13 Dec 2020 02:32:06
User entered 'No (N)'	System	13 Dec 2020 02:32:06

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Have you been exposed to someone with 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 (b9c41a5b25988163)', Time: '2020-12-12T21:32:30', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '7fb51eca-1d13-4c21-bdf0-9fda223147fd'	System	13 Dec 2020 02:32:06
User entered 'No (N)'	System	13 Dec 2020 02:32:06

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-12-12T21:32:36', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '7fb51eca-1d13-4c21-bdf0-9fda223147fd'	System	13 Dec 2020 02:32:06
User entered '12 Dec 2020 21:32:36'	System	13 Dec 2020 02:32:06

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[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 (b9c41a5b25988163)', Time: '2020-12-18T13:49:35', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '516d7d9f-5ac1-4ff3-8426-f463f37fee4e'	System	18 Dec 2020 18:49:09
User entered 'No (N)'	System	18 Dec 2020 18:49:09

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

Have you been exposed to someone with 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 (b9c41a5b25988163)', Time: '2020-12-18T13:49:38', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '516d7d9f-5ac1-4ff3-8426-f463f37fee4e'	System	18 Dec 2020 18:49:09
User entered 'No (N)'	System	18 Dec 2020 18:49:09

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-12-18T13:49:45', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '516d7d9f-5ac1-4ff3-8426-f463f37fee4e'	System	18 Dec 2020 18:49:09
User entered '18 Dec 2020 13:49:45'	System	18 Dec 2020 18:49:09

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[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 (b9c41a5b25988163)', Time: '2020-12-28T11:59:08', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '7fef486a-012e-4ecb-9b96-e751f8bf8142'	System	28 Dec 2020 16:58:22
User entered 'No (N)'	System	28 Dec 2020 16:58:22

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

Have you been exposed to someone with 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 (b9c41a5b25988163)', Time: '2020-12-28T11:59:10', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '7fef486a-012e-4ecb-9b96-e751f8bf8142'	System	28 Dec 2020 16:58:22
User entered 'No (N)'	System	28 Dec 2020 16:58:22

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2020-12-28T11:59:13', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '7fef486a-012e-4ecb-9b96-e751f8bf8142'	System	28 Dec 2020 16:58:22
User entered '28 Dec 2020 11:59:13'	System	28 Dec 2020 16:58:22

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[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 (b9c41a5b25988163)', Time: '2021-01-01T09:17:04', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '1910c529-7d60-425f-8f71-3ca254292a97'	System	01 Jan 2021 14:16:14
User entered 'No (N)'	System	01 Jan 2021 14:16:14

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

Have you been exposed to someone with 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 (b9c41a5b25988163)', Time: '2021-01-01T09:17:06', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '1910c529-7d60-425f-8f71-3ca254292a97'	System	01 Jan 2021 14:16:14
User entered 'No (N)'	System	01 Jan 2021 14:16:14

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2021-01-01T09:17:10', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '1910c529-7d60-425f-8f71-3ca254292a97'	System	01 Jan 2021 14:16:14
User entered '01 Jan 2021 09:17:10'	System	01 Jan 2021 14:16:14

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[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 (b9c41a5b25988163)', Time: '2021-01-10T00:21:31', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: 'a7e3b194-e374-448c-a9c9-abf77aa11450'	System	10 Jan 2021 05:20:35
User entered 'No (N)'	System	10 Jan 2021 05:20:35

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

Have you been exposed to someone with 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 (b9c41a5b25988163)', Time: '2021-01-10T00:21:34', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: 'a7e3b194-e374-448c-a9c9-abf77aa11450'	System	10 Jan 2021 05:20:35
User entered 'No (N)'	System	10 Jan 2021 05:20:35

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2021-01-10T00:21:41', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: 'a7e3b194-e374-448c-a9c9-abf77aa11450'	System	10 Jan 2021 05:20:35
User entered '10 Jan 2021 00:21:41'	System	10 Jan 2021 05:20:35

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[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 (b9c41a5b25988163)', Time: '2021-01-16T02:23:09', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: 'c6392801-2e23-457a-a207-f40aabafa487'	System	16 Jan 2021 07:22:17
User entered 'No (N)'	System	16 Jan 2021 07:22:17

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

Have you been exposed to someone with 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 (b9c41a5b25988163)', Time: '2021-01-16T02:23:12', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: 'c6392801-2e23-457a-a207-f40aabafa487'	System	16 Jan 2021 07:22:17
User entered 'No (N)'	System	16 Jan 2021 07:22:17

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2021-01-16T02:23:17', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: 'c6392801-2e23-457a-a207-f40aabafa487'	System	16 Jan 2021 07:22:17
User entered '16 Jan 2021 02:23:17'	System	16 Jan 2021 07:22:17

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[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 (b9c41a5b25988163)', Time: '2021-01-22T14:09:15', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: 'cc545331-a5d2-4f56-8e03-dbadc49864a3'	System	22 Jan 2021 19:07:59
User entered 'No (N)'	System	22 Jan 2021 19:07:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

Have you been exposed to someone with 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 (b9c41a5b25988163)', Time: '2021-01-22T14:09:17', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: 'cc545331-a5d2-4f56-8e03-dbadc49864a3'	System	22 Jan 2021 19:07:59
User entered 'No (N)'	System	22 Jan 2021 19:07:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2021-01-22T14:09:24', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: 'cc545331-a5d2-4f56-8e03-dbadc49864a3'	System	22 Jan 2021 19:07:59
User entered '22 Jan 2021 14:09:24'	System	22 Jan 2021 19:07:59

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[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 (b9c41a5b25988163)', Time: '2021-01-29T23:42:01', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '84648078-9842-4598-b547-48c4c7ebb5e8'	System	30 Jan 2021 04:40:29
User entered 'No (N)'	System	30 Jan 2021 04:40:29

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

Have you been exposed to someone with 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 (b9c41a5b25988163)', Time: '2021-01-29T23:42:07', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '84648078-9842-4598-b547-48c4c7ebb5e8'	System	30 Jan 2021 04:40:29
User entered 'No (N)'	System	30 Jan 2021 04:40:29

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2021-01-29T23:42:11', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '84648078-9842-4598-b547-48c4c7ebb5e8'	System	30 Jan 2021 04:40:29
User entered '29 Jan 2021 23:42:11'	System	30 Jan 2021 04:40:29

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[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 (b9c41a5b25988163)', Time: '2021-02-05T07:49:37', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '03385de5-5eff-4953-b33b-905b2eba435a'	System	05 Feb 2021 12:47:55
User entered 'No (N)'	System	05 Feb 2021 12:47:55

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

Have you been exposed to someone with 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 (b9c41a5b25988163)', Time: '2021-02-05T07:49:40', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '03385de5-5eff-4953-b33b-905b2eba435a'	System	05 Feb 2021 12:47:55
User entered 'No (N)'	System	05 Feb 2021 12:47:55

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2021-02-05T07:49:43', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '03385de5-5eff-4953-b33b-905b2eba435a'	System	05 Feb 2021 12:47:55
User entered '05 Feb 2021 07:49:43'	System	05 Feb 2021 12:47:55

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[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 (b9c41a5b25988163)', Time: '2021-02-13T07:26:09', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: 'b4008863-9c1a-4a66-af8b-99f498809856'	System	13 Feb 2021 12:24:20
User entered 'No (N)'	System	13 Feb 2021 12:24:20

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

Have you been exposed to someone with 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 (b9c41a5b25988163)', Time: '2021-02-13T07:26:12', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: 'b4008863-9c1a-4a66-af8b-99f498809856'	System	13 Feb 2021 12:24:20
User entered 'No (N)'	System	13 Feb 2021 12:24:20

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2021-02-13T07:26:18', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: 'b4008863-9c1a-4a66-af8b-99f498809856'	System	13 Feb 2021 12:24:20
User entered '13 Feb 2021 07:26:18'	System	13 Feb 2021 12:24:20

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '12 Feb 2021 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '16 Feb 2021 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[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 (b9c41a5b25988163)', Time: '2021-02-19T01:55:15', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: 'afa0f434-84d6-4c51-ad86-53b83a4939c1'	System	19 Feb 2021 06:53:15
User entered 'No (N)'	System	19 Feb 2021 06:53:15

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

Have you been exposed to someone with 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 (b9c41a5b25988163)', Time: '2021-02-19T01:55:19', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: 'afa0f434-84d6-4c51-ad86-53b83a4939c1'	System	19 Feb 2021 06:53:15
User entered 'No (N)'	System	19 Feb 2021 06:53:15

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2021-02-19T01:55:23', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: 'afa0f434-84d6-4c51-ad86-53b83a4939c1'	System	19 Feb 2021 06:53:15
User entered '19 Feb 2021 01:55:23'	System	19 Feb 2021 06:53:15

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '19 Feb 2021 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '23 Feb 2021 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[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 (b9c41a5b25988163)', Time: '2021-02-26T16:04:18', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '996e695c-c319-4111-ae54-3a16eddc203d'	System	26 Feb 2021 21:02:14
User entered 'No (N)'	System	26 Feb 2021 21:02:14

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

Have you been exposed to someone with 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 (b9c41a5b25988163)', Time: '2021-02-26T16:04:21', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '996e695c-c319-4111-ae54-3a16eddc203d'	System	26 Feb 2021 21:02:14
User entered 'No (N)'	System	26 Feb 2021 21:02:14

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2021-02-26T16:04:26', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '996e695c-c319-4111-ae54-3a16eddc203d'	System	26 Feb 2021 21:02:14
User entered '26 Feb 2021 16:04:26'	System	26 Feb 2021 21:02:14

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '26 Feb 2021 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '02 Mar 2021 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[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 (b9c41a5b25988163)', Time: '2021-03-05T08:28:29', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '1da62838-f71c-4a79-9b3b-c0e4140e5880'	System	05 Mar 2021 13:26:38
User entered 'Yes (Y)'	System	05 Mar 2021 13:26:38

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Have you been exposed to someone with 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 (b9c41a5b25988163)', Time: '2021-03-05T08:28:36', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '1da62838-f71c-4a79-9b3b-c0e4140e5880'	System	05 Mar 2021 13:26:38
User entered 'No (N)'	System	05 Mar 2021 13:26:38

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2021-03-05T08:29:00', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '1da62838-f71c-4a79-9b3b-c0e4140e5880'	System	05 Mar 2021 13:26:38
User entered 'No (N)'	System	05 Mar 2021 13:26:38

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2021-03-05T08:29:08', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '1da62838-f71c-4a79-9b3b-c0e4140e5880'	System	05 Mar 2021 13:26:38
User entered 'No (N)'	System	05 Mar 2021 13:26:38

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2021-03-05T08:29:12', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '1da62838-f71c-4a79-9b3b-c0e4140e5880'	System	05 Mar 2021 13:26:38
User entered '05 Mar 2021 08:29:12'	System	05 Mar 2021 13:26:38

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '05 Mar 2021 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '09 Mar 2021 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[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 (b9c41a5b25988163)', Time: '2021-03-14T00:05:35', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '66db86aa-a826-4b97-bc63-f55bf54d2bee'	System	14 Mar 2021 05:08:12
User entered 'Yes (Y)'	System	14 Mar 2021 05:08:12

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

Have you been exposed to someone with 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 (b9c41a5b25988163)', Time: '2021-03-14T00:05:44', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '66db86aa-a826-4b97-bc63-f55bf54d2bee'	System	14 Mar 2021 05:08:12
User entered 'No (N)'	System	14 Mar 2021 05:08:12

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2021-03-14T00:05:53', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '66db86aa-a826-4b97-bc63-f55bf54d2bee'	System	14 Mar 2021 05:08:12
User entered 'No (N)'	System	14 Mar 2021 05:08:12

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2021-03-14T00:06:05', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '66db86aa-a826-4b97-bc63-f55bf54d2bee'	System	14 Mar 2021 05:08:12
User entered 'Yes (Y)'	System	14 Mar 2021 05:08:12

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Please 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 (b9c41a5b25988163)', Time: '2021-03-14T00:06:15', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '66db86aa-a826-4b97-bc63-f55bf54d2bee'	System	14 Mar 2021 05:08:12
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	14 Mar 2021 05:08:12

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2021-03-14T00:06:41', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '66db86aa-a826-4b97-bc63-f55bf54d2bee'	System	14 Mar 2021 05:08:12
User entered '14 Mar 2021 00:06:41'	System	14 Mar 2021 05:08:12

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '12 Mar 2021 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '16 Mar 2021 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[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 (b9c41a5b25988163)', Time: '2021-03-19T00:21:33', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '8f8bff71-4a93-46a2-96f3-036e1498edbf'	System	19 Mar 2021 04:18:49
User entered 'No (N)'	System	19 Mar 2021 04:18:49

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

Have you been exposed to someone with 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 (b9c41a5b25988163)', Time: '2021-03-19T00:21:40', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '8f8bff71-4a93-46a2-96f3-036e1498edbf'	System	19 Mar 2021 04:18:49
User entered 'No (N)'	System	19 Mar 2021 04:18:49

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2021-03-19T00:21:44', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '8f8bff71-4a93-46a2-96f3-036e1498edbf'	System	19 Mar 2021 04:18:49
User entered '19 Mar 2021 00:21:44'	System	19 Mar 2021 04:18:49

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '19 Mar 2021 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '23 Mar 2021 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[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 (b9c41a5b25988163)', Time: '2021-03-27T15:28:54', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '4fade8db-8ba9-42ab-b73b-bed01a090254'	System	27 Mar 2021 19:25:52
User entered 'No (N)'	System	27 Mar 2021 19:25:52

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

Have you been exposed to someone with 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 (b9c41a5b25988163)', Time: '2021-03-27T15:28:57', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '4fade8db-8ba9-42ab-b73b-bed01a090254'	System	27 Mar 2021 19:25:52
User entered 'No (N)'	System	27 Mar 2021 19:25:52

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2021-03-27T15:29:01', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '4fade8db-8ba9-42ab-b73b-bed01a090254'	System	27 Mar 2021 19:25:52
User entered '27 Mar 2021 15:29:01'	System	27 Mar 2021 19:25:52

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '26 Mar 2021 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '30 Mar 2021 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[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 (b9c41a5b25988163)', Time: '2021-04-02T10:06:03', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '485c7dc1-7e66-485d-8a3e-acbf47b9f59f'	System	02 Apr 2021 14:02:44
User entered 'No (N)'	System	02 Apr 2021 14:02:44

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

Have you been exposed to someone with 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 (b9c41a5b25988163)', Time: '2021-04-02T10:06:05', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '485c7dc1-7e66-485d-8a3e-acbf47b9f59f'	System	02 Apr 2021 14:02:44
User entered 'No (N)'	System	02 Apr 2021 14:02:44

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2021-04-02T10:06:10', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '485c7dc1-7e66-485d-8a3e-acbf47b9f59f'	System	02 Apr 2021 14:02:44
User entered '02 Apr 2021 10:06:10'	System	02 Apr 2021 14:02:44

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '02 Apr 2021 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '06 Apr 2021 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[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 (b9c41a5b25988163)', Time: '2021-04-10T20:24:41', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: 'cb15a9ee-840c-40ab-86ea-d60bf70e365c'	System	11 Apr 2021 00:21:17
User entered 'No (N)'	System	11 Apr 2021 00:21:17

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

Have you been exposed to someone with 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 (b9c41a5b25988163)', Time: '2021-04-10T20:24:43', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: 'cb15a9ee-840c-40ab-86ea-d60bf70e365c'	System	11 Apr 2021 00:21:17
User entered 'No (N)'	System	11 Apr 2021 00:21:17

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2021-04-10T20:24:48', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: 'cb15a9ee-840c-40ab-86ea-d60bf70e365c'	System	11 Apr 2021 00:21:17
User entered '10 Apr 2021 20:24:48'	System	11 Apr 2021 00:21:17

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '09 Apr 2021 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '13 Apr 2021 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[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 (b9c41a5b25988163)', Time: '2021-04-16T23:05:57', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '5fdfb1f3-581c-4828-af53-84e148fb8ece'	System	17 Apr 2021 03:02:14
User entered 'No (N)'	System	17 Apr 2021 03:02:14

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

Have you been exposed to someone with 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 (b9c41a5b25988163)', Time: '2021-04-16T23:06:00', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '5fdfb1f3-581c-4828-af53-84e148fb8ece'	System	17 Apr 2021 03:02:14
User entered 'No (N)'	System	17 Apr 2021 03:02:14

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2021-04-16T23:06:04', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '5fdfb1f3-581c-4828-af53-84e148fb8ece'	System	17 Apr 2021 03:02:14
User entered '16 Apr 2021 23:06:04'	System	17 Apr 2021 03:02:14

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '16 Apr 2021 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '20 Apr 2021 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[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 (b9c41a5b25988163)', Time: '2021-04-23T00:13:32', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '3e00ff65-30a6-4d5d-9ee5-f96a4723c2f0'	System	23 Apr 2021 04:09:38
User entered 'No (N)'	System	23 Apr 2021 04:09:38

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

Have you been exposed to someone with 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 (b9c41a5b25988163)', Time: '2021-04-23T00:13:35', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '3e00ff65-30a6-4d5d-9ee5-f96a4723c2f0'	System	23 Apr 2021 04:09:38
User entered 'No (N)'	System	23 Apr 2021 04:09:38

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2021-04-23T00:13:40', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '3e00ff65-30a6-4d5d-9ee5-f96a4723c2f0'	System	23 Apr 2021 04:09:38
User entered '23 Apr 2021 00:13:40'	System	23 Apr 2021 04:09:38

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '23 Apr 2021 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '27 Apr 2021 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[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 (b9c41a5b25988163)', Time: '2021-04-30T07:13:54', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '80e976e4-180e-4709-97b6-b1ad93ce3443'	System	30 Apr 2021 11:09:47
User entered 'No (N)'	System	30 Apr 2021 11:09:47

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

Have you been exposed to someone with 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 (b9c41a5b25988163)', Time: '2021-04-30T07:13:57', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '80e976e4-180e-4709-97b6-b1ad93ce3443'	System	30 Apr 2021 11:09:47
User entered 'No (N)'	System	30 Apr 2021 11:09:47

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2021-04-30T07:14:02', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '80e976e4-180e-4709-97b6-b1ad93ce3443'	System	30 Apr 2021 11:09:47
User entered '30 Apr 2021 07:14:02'	System	30 Apr 2021 11:09:47

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '30 Apr 2021 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '04 May 2021 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '07 May 2021 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '11 May 2021 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '14 May 2021 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '18 May 2021 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '21 May 2021 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '25 May 2021 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '28 May 2021 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '01 Jun 2021 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '04 Jun 2021 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '08 Jun 2021 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '11 Jun 2021 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '15 Jun 2021 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '18 Jun 2021 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '22 Jun 2021 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '25 Jun 2021 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '29 Jun 2021 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '02 Jul 2021 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '06 Jul 2021 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '09 Jul 2021 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '13 Jul 2021 23:59'	System	19 Nov 2020 22:53:02

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '16 Jul 2021 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '20 Jul 2021 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '23 Jul 2021 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '27 Jul 2021 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '30 Jul 2021 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '03 Aug 2021 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '06 Aug 2021 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '10 Aug 2021 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '13 Aug 2021 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '17 Aug 2021 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '20 Aug 2021 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '24 Aug 2021 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '27 Aug 2021 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '31 Aug 2021 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '03 Sep 2021 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '07 Sep 2021 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '10 Sep 2021 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '14 Sep 2021 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '17 Sep 2021 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '21 Sep 2021 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '24 Sep 2021 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '28 Sep 2021 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '01 Oct 2021 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '05 Oct 2021 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '08 Oct 2021 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '12 Oct 2021 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '15 Oct 2021 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '19 Oct 2021 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '22 Oct 2021 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '26 Oct 2021 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '29 Oct 2021 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '02 Nov 2021 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '05 Nov 2021 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '09 Nov 2021 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '12 Nov 2021 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '16 Nov 2021 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '19 Nov 2021 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '23 Nov 2021 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '26 Nov 2021 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '30 Nov 2021 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '03 Dec 2021 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '07 Dec 2021 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '10 Dec 2021 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '14 Dec 2021 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '17 Dec 2021 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '21 Dec 2021 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '24 Dec 2021 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '28 Dec 2021 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '31 Dec 2021 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '04 Jan 2022 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '07 Jan 2022 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '11 Jan 2022 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '14 Jan 2022 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '18 Jan 2022 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '21 Jan 2022 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '25 Jan 2022 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '28 Jan 2022 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '01 Feb 2022 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '04 Feb 2022 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '08 Feb 2022 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '11 Feb 2022 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '15 Feb 2022 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '18 Feb 2022 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '22 Feb 2022 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '25 Feb 2022 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '01 Mar 2022 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '04 Mar 2022 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '08 Mar 2022 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '11 Mar 2022 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '15 Mar 2022 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '18 Mar 2022 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '22 Mar 2022 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '25 Mar 2022 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '29 Mar 2022 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '01 Apr 2022 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '05 Apr 2022 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '08 Apr 2022 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '12 Apr 2022 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '15 Apr 2022 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '19 Apr 2022 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '22 Apr 2022 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '26 Apr 2022 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '29 Apr 2022 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '03 May 2022 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '06 May 2022 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '10 May 2022 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '13 May 2022 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '17 May 2022 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '20 May 2022 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '24 May 2022 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '27 May 2022 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '31 May 2022 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '03 Jun 2022 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '07 Jun 2022 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '10 Jun 2022 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '14 Jun 2022 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '17 Jun 2022 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '21 Jun 2022 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '24 Jun 2022 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '28 Jun 2022 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '01 Jul 2022 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '05 Jul 2022 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '08 Jul 2022 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '12 Jul 2022 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '15 Jul 2022 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '19 Jul 2022 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '22 Jul 2022 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '26 Jul 2022 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '29 Jul 2022 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '02 Aug 2022 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '05 Aug 2022 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '09 Aug 2022 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '12 Aug 2022 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '16 Aug 2022 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '19 Aug 2022 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '23 Aug 2022 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '26 Aug 2022 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '30 Aug 2022 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '02 Sep 2022 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '06 Sep 2022 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '09 Sep 2022 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '13 Sep 2022 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '16 Sep 2022 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '20 Sep 2022 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '23 Sep 2022 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '27 Sep 2022 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '30 Sep 2022 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '04 Oct 2022 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '07 Oct 2022 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '11 Oct 2022 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '14 Oct 2022 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '18 Oct 2022 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '21 Oct 2022 00:01'	System	19 Nov 2020 22:53:02

US3672187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:53:02
Amendment Manager: User entered '25 Oct 2022 23:59'	System	19 Nov 2020 22:53:02

US3672187

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:22:10

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 02:23:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2021-02-28T21:06:03', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '8165a285-fc82-415f-8df2-d454b06ebdb2'	System	01 Mar 2021 02:12:51
User entered 'No (N)'	System	01 Mar 2021 02:12:51

US3672187

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:22:10

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:23:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9c41a5b25988163)', Time: '2021-02-28T21:06:06', User OID: 'PatientReportedOutcome (US3672187)', ODM File OID: '8165a285-fc82-415f-8df2-d454b06ebdb2'	System	01 Mar 2021 02:12:51
User entered '28 Feb 2021 21:06:06'	System	01 Mar 2021 02:12:51

US3672187

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Nov 2020 21:16:04

US3672187

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:21
User entered '16 Nov 2020'	(b) (4), (b) (6)	16 Nov 2020 21:16:04

US3672187

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:21
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	16 Nov 2020 21:16:04

US3672187

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:10

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:21
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 21:16:04

US3672187

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Nov 2020 21:16:09

US3672187

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:01:58
User entered 'I'	System	16 Nov 2020 21:16:09

US3672187

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:10:47
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Dec 2020 22:06:33

US3672187

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:10:47
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:21
User entered '22 Dec 2020'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:06:33

US3672187

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:10:47
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:21
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:06:33

US3672187

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:10

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:10:47
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:21
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:06:33

US3672187

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:10:47
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:06:37

US3672187

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:10:47
User entered 'I'	System	28 Dec 2020 22:06:37

US3672187

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:10:47
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Feb 2021 18:38:43

US3672187

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:10:47
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:21
User entered '18 Jan 2021'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:38:43

US3672187

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:10:47
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:21
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	01 Feb 2021 18:38:43

US3672187

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:10

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:10:47
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:21
User entered empty.	(b) (4), (b) (6)	01 Feb 2021 18:38:43

US3672187

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:10:47
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Feb 2021 18:38:47

US3672187

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:10:47
User entered 'I'	System	01 Feb 2021 18:38:47

US3672187

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:10:47
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Feb 2021 18:38:56

US3672187

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:10:47
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:21
User entered '17 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Feb 2021 18:08:21
User entered '01 Feb 2021'	(b) (4), (b) (6)	01 Feb 2021 18:38:56

US3672187

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:10:47
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:21
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	01 Feb 2021 18:38:56

US3672187

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:10

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:10:47
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:21
User entered empty.	(b) (4), (b) (6)	01 Feb 2021 18:38:56

US3672187

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:10:47
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Feb 2021 18:39:00

US3672187

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:10:47
User entered 'I'	System	01 Feb 2021 18:39:00

US3672187

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:22:10

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 17:39:51

US3672187

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:57
User entered '31 Mar 2021'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 17:39:51

US3672187

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:22:10

[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 15:08:57
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 17:39:51

US3672187

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:22:10

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	01 Apr 2021 17:39:51

US3672187

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 17:40:03

US3672187

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:57
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 17:40:03

US3672187

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:57
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 17:40:03

US3672187

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 17:40:03

US3672187

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:57
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 17:40:03

US3672187

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:10

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:57
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 17:40:03

US3672187

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:10

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:57
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 17:40:03

US3672187

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:57
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 17:40:03

US3672187

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:10

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 17:40:03

US3672187

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:57
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 17:40:03

US3672187

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 17:40:03

US3672187

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:57
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 17:40:03

US3672187

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:10

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 17:40:03

US3672187

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:57
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 17:40:03

US3672187

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:10

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 17:40:03

US3672187

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:22:10

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 17:40:14

US3672187

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:22:10

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 17:40:14

US3672187

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:22:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 17:40:31

US3672187

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:22:10

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
User entered '31 Mar 2021'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 17:40:31

US3672187

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
User entered '13:10'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 17:40:31

US3672187

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
User entered '31 Mar 2021 13:10'	System	01 Apr 2021 17:40:31

US3672187

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 17:40:37

US3672187

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:10

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Apr 2021 17:40:37

US3672187

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

Form: Visit Date

Generated On: 10 Jun 2021 09:22:10

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 14:58:53

US3672187

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

Form: Visit Date

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered '25 Jan 2021'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 14:58:53

US3672187

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

Form: Visit Date

Generated On: 10 Jun 2021 09:22:10

[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 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 14:58:53

US3672187

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

Form: Visit Date

Generated On: 10 Jun 2021 09:22:10

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User entered 'UNBLND_DECIDE'	System	25 Jan 2021 14:58:53

US3672187

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

Form: Unblinding

Generated On: 10 Jun 2021 09:22:10

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered '25 Jan 2021'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 14:59:19

US3672187

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

Form: Unblinding

Generated On: 10 Jun 2021 09:22:10

[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 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 13:38:43
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 05:44:52

US3672187

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

Form: Unblinding

Generated On: 10 Jun 2021 09:22:10

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 14:59:19

US3672187

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

Form: Unblinding

Generated On: 10 Jun 2021 09:22:10

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
User closed query 'Per CDM, per sponsor review: Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Apr 2021 14:32:52
Query 'Per CDM, per sponsor review: Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 13:38:45
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4), (b) (6)	09 Apr 2021 13:38:43
User opened query 'Per CDM, per sponsor review: Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 08:31:23
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 05:44:52

US3672187

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

Form: Unblinding

Generated On: 10 Jun 2021 09:22:10

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered '25 Jan 2021'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 14:59:19

US3672187

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

Form: Unblinding

Generated On: 10 Jun 2021 09:22:10

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 14:59:19

US3672187

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

Form: Unblinding

Generated On: 10 Jun 2021 09:22:10

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 14:59:19

US3672187

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

Form: Unblinding

Generated On: 10 Jun 2021 09:22:10

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered 'Not Administered (NA)'	(b) (4), (b) (6)	25 Jan 2021 14:59:19

US3672187

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

Form: Unblinding

Generated On: 10 Jun 2021 09:22:10

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 14:59:19

US3672187

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

Form: Unblinding

Generated On: 10 Jun 2021 09:22:10

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User entered 'I'	System	25 Jan 2021 14:59:19

US3672187

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

Form: Unblinding

Generated On: 10 Jun 2021 09:22:10

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User entered 'I'	System	25 Jan 2021 14:59:19

US3672187

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:22:10

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered '170.0' cm	(b) (4) (b) (4), (b) (6)	25 Jan 2021 15:01:10

US3672187

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:22:10

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered '105.7' kg	(b) (4) (b) (4), (b) (6)	25 Jan 2021 15:01:10

US3672187

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:22:10

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User entered '36.57439'	System	25 Jan 2021 15:01:10
DataPoint set to visible.	System	25 Jan 2021 14:59:19

US3672187

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:22:10

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered '170.0' cm	(b) (4) (b) (4), (b) (6)	25 Jan 2021 15:01:10

US3672187

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:22:10

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered '105.7' kg	(b) (4) (b) (4), (b) (6)	25 Jan 2021 15:01:10

US3672187

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:22:10

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User entered '36.57439'	System	25 Jan 2021 15:01:10
DataPoint set to visible.	System	25 Jan 2021 14:59:19

US3672187

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:10

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	25 Jan 2021 15:01:10

US3672187

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 15:01:10

US3672187

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered '25 Jan 2021'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 15:01:10

US3672187

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered '09:17'	(b) (4), (b) (6)	25 Jan 2021 15:01:10

US3672187

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User entered '25 Jan 2021 09:17'	System	25 Jan 2021 15:01:10

US3672187

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered '98.7' F	(b) (4), (b) (6)	25 Jan 2021 15:01:10

US3672187

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 15:01:10

US3672187

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:10

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 15:01:10

US3672187

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered '86'	(b) (4), (b) (6)	25 Jan 2021 15:01:10

US3672187

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:10

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User entered 'bpm'	System	25 Jan 2021 15:01:10

US3672187

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered '16'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 15:01:10

US3672187

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User entered 'breaths/min'	System	25 Jan 2021 15:01:10

US3672187

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered '139'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 15:01:10

US3672187

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:10

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User entered 'mmHg'	System	25 Jan 2021 15:01:10

US3672187

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered '88'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 15:01:10

US3672187

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:10

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User entered 'mmHg'	System	25 Jan 2021 15:01:10

US3672187

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:22:10

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered '170.0' cm	(b) (4) (b) (4), (b) (6)	25 Jan 2021 15:01:10

US3672187

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:22:10

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered '105.7' kg	(b) (4) (b) (4), (b) (6)	25 Jan 2021 15:01:10

US3672187

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:22:10

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User entered '36.57439'	System	25 Jan 2021 15:01:10
DataPoint set to visible.	System	25 Jan 2021 14:59:19

US3672187

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:10

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	25 Jan 2021 15:01:10

US3672187

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	23 Feb 2021 21:46:40
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Feb 2021 21:46:40
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Feb 2021 21:46:40
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Jan 2021 15:01:10
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 15:01:10

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered '25 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Feb 2021 21:46:40
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 15:01:10

US3672187

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered '10:20' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Feb 2021 21:46:40
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 15:01:10

US3672187

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User entered '25 Jan 2021 10:20'	System	23 Feb 2021 21:46:40
User entered empty.	System	25 Jan 2021 15:01:10

US3672187

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered '98.7' F reason for change: Data Entry Error	(b) (4), (b) (6)	23 Feb 2021 21:46:40
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 15:01:10

US3672187

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Feb 2021 21:46:40
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 15:01:10

US3672187

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:10

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 15:01:10

US3672187

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered '92' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Feb 2021 21:46:40
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 15:01:10

US3672187

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:10

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User entered 'bpm'	System	23 Feb 2021 21:46:40
User entered empty.	System	25 Jan 2021 15:01:10

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered '14' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Feb 2021 21:46:40
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 15:01:10

US3672187

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User entered 'breaths/min'	System	23 Feb 2021 21:46:40
User entered empty.	System	25 Jan 2021 15:01:10

US3672187

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered '140' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Feb 2021 21:46:40
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 15:01:10

US3672187

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:10

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User entered 'mmHg'	System	23 Feb 2021 21:46:40
User entered empty.	System	25 Jan 2021 15:01:10

US3672187

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered '90' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Feb 2021 21:46:40
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 15:01:10

US3672187

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:10

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User entered 'mmHg'	System	23 Feb 2021 21:46:40
User entered empty.	System	25 Jan 2021 15:01:10

US3672187

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

Form: Physical Examination

Generated On: 10 Jun 2021 09:22:10

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 15:01:20

US3672187

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

Form: Physical Examination

Generated On: 10 Jun 2021 09:22:10

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered '25 Jan 2021'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 15:01:20

US3672187

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

Form: Exposure

Generated On: 10 Jun 2021 09:22:10

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 15:59:18

US3672187

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

Form: Exposure

Generated On: 10 Jun 2021 09:22:10

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 15:59:18

US3672187

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

Form: Exposure

Generated On: 10 Jun 2021 09:22:10

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 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 15:59:18

US3672187

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

Form: Exposure

Generated On: 10 Jun 2021 09:22:10

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User entered 'mRNA-1273'	System	25 Jan 2021 15:59:18
DataPoint set to visible.	System	25 Jan 2021 14:59:19

US3672187

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

Form: Exposure

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered '25 Jan 2021'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 15:59:18

US3672187

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

Form: Exposure

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered '09:42'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 15:59:18

US3672187

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

Form: Exposure

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User entered '25 Jan 2021 09:42'	System	25 Jan 2021 15:59:18

US3672187

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

Form: Exposure

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 15:59:18

US3672187

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

Form: Exposure

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User entered 'ONCE'	System	25 Jan 2021 15:59:18

US3672187

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

Form: Exposure

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User entered 'INTRAMUSCULAR'	System	25 Jan 2021 15:59:18

US3672187

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:22:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 15:01:40

US3672187

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:22:10

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered '25 Jan 2021'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 15:01:40

US3672187

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered '09:32'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 15:01:40

US3672187

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User entered '25 Jan 2021 09:32'	System	25 Jan 2021 15:01:40

US3672187

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:22:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 15:01:52

US3672187

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:22:10

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered '25 Jan 2021'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 15:01:52

US3672187

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered '09:10'	(b) (4), (b) (6)	25 Jan 2021 15:01:52

US3672187

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User entered '25 Jan 2021 09:10'	System	25 Jan 2021 15:01:52

US3672187

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

Form: Continuing

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 15:01:56

US3672187

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

Form: Continuing

Generated On: 10 Jun 2021 09:22:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User entered 'I'	System	25 Jan 2021 15:01:56

US3672187

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:44:19

US3672187

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:21
User entered '01 Feb 2021'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:44:19

US3672187

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:21
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:44:19

US3672187

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:10

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:21
User entered empty.	(b) (4), (b) (6)	01 Feb 2021 18:44:19

US3672187

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:44:23

US3672187

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User entered 'I'	System	01 Feb 2021 18:44:23

US3672187

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:10

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User entered '1'	System	01 Feb 2021 18:44:23
DataPoint set to visible.	System	01 Feb 2021 18:44:23

US3672187

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:22:10

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Mar 2021 14:54:55

US3672187

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
User entered '05 Mar 2021'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:54:55

US3672187

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:22:10

[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 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:54:55

US3672187

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:22:10

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User entered 'OLD29'	System	11 Mar 2021 14:54:55

US3672187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:10

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	11 Mar 2021 14:55:38

US3672187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:55:38

US3672187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
User entered '05 Mar 2021'	(b) (4), (b) (6)	11 Mar 2021 14:55:38

US3672187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	11 Mar 2021 14:56:57
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	11 Mar 2021 14:56:57
User entered '09:39' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Mar 2021 14:56:57
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Mar 2021 14:55:38
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 14:55:38

US3672187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User entered '05 Mar 2021 09:39'	System	11 Mar 2021 14:56:57
User entered empty.	System	11 Mar 2021 14:55:38

US3672187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
User entered '98.0' F	(b) (4), (b) (6)	11 Mar 2021 14:55:38

US3672187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:55:38

US3672187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:10

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:55:38

US3672187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
User entered '90'	(b) (4), (b) (6)	11 Mar 2021 14:55:38

US3672187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:10

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User entered 'bpm'	System	11 Mar 2021 14:55:38

US3672187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
User entered '18'	(b) (4), (b) (6)	11 Mar 2021 14:55:38

US3672187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User entered 'breaths/min'	System	11 Mar 2021 14:55:38

US3672187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
User entered '139'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:55:38

US3672187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:10

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User entered 'mmHg'	System	11 Mar 2021 14:55:38

US3672187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
User entered '81'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:55:38

US3672187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:10

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User entered 'mmHg'	System	11 Mar 2021 14:55:38

US3672187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:10

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	11 Mar 2021 14:56:23

US3672187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:56:23

US3672187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
User entered '05 Mar 2021'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:56:23

US3672187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	11 Mar 2021 14:56:57
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	11 Mar 2021 14:56:57
User entered '10:51' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Mar 2021 14:56:57
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Mar 2021 14:56:23
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 14:56:23

US3672187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User entered '05 Mar 2021 10:51'	System	11 Mar 2021 14:56:57
User entered empty.	System	11 Mar 2021 14:56:23

US3672187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
User entered '98.0' F	(b) (4), (b) (6)	11 Mar 2021 14:56:23

US3672187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:56:23

US3672187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:10

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 14:56:23

US3672187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
User entered '97'	(b) (4), (b) (6)	11 Mar 2021 14:56:23

US3672187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:10

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User entered 'bpm'	System	11 Mar 2021 14:56:23

US3672187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
User entered '18'	(b) (4), (b) (6)	11 Mar 2021 14:56:23

US3672187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User entered 'breaths/min'	System	11 Mar 2021 14:56:23

US3672187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
User entered '134'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:56:23

US3672187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:10

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User entered 'mmHg'	System	11 Mar 2021 14:56:23

US3672187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
User entered '87'	(b) (4), (b) (6)	11 Mar 2021 14:56:23

US3672187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:10

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User entered 'mmHg'	System	11 Mar 2021 14:56:23

US3672187

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:22:10

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:57:12

US3672187

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:22:10

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
User entered '05 Mar 2021'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:57:12

US3672187

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:22:10

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:58:41

US3672187

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:22:10

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 14:58:41

US3672187

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:22:10

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 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 14:58:41

US3672187

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:22:10

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User entered 'mRNA-1273'	System	11 Mar 2021 14:58:41
DataPoint set to visible.	System	01 Feb 2021 18:44:23

US3672187

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
User entered '05 Mar 2021'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:58:41

US3672187

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
User entered '10:15'	(b) (4), (b) (6)	11 Mar 2021 14:58:41

US3672187

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User entered '05 Mar 2021 10:15'	System	11 Mar 2021 14:58:41

US3672187

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:58:41

US3672187

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User entered 'ONCE'	System	11 Mar 2021 14:58:41

US3672187

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User entered 'INTRAMUSCULAR'	System	11 Mar 2021 14:58:41

US3672187

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:58:46

US3672187

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User entered 'I'	System	11 Mar 2021 14:58:46

US3672187

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Apr 2021 17:28:32

US3672187

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
User entered '12 Mar 2021'	(b) (4), (b) (6)	01 Apr 2021 17:28:32

US3672187

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	01 Apr 2021 17:28:32

US3672187

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:10

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 17:28:32

US3672187

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Apr 2021 17:28:36

US3672187

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:45
User entered 'I'	System	01 Apr 2021 17:28:36

US3672187

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:22:10

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:12:49

US3672187

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
User entered '6 Apr 2021'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:12:49

US3672187

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:22:10

[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 15:08:27
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:12:49

US3672187

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:22:10

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	06 Apr 2021 14:12:49

US3672187

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:12:54

US3672187

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:12:54

US3672187

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:12:54

US3672187

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 14:12:54

US3672187

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:12:54

US3672187

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:10

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:12:54

US3672187

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:10

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:12:54

US3672187

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:12:54

US3672187

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:10

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 14:12:54

US3672187

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:12:54

US3672187

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 14:12:54

US3672187

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:12:54

US3672187

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:10

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 14:12:54

US3672187

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:12:54

US3672187

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:10

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 14:12:54

US3672187

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:22:10

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:12:58

US3672187

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:22:10

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:12:58

US3672187

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:22:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:13:09

US3672187

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
User entered '6 Apr 2021'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:13:09

US3672187

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
User entered '10:07'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:13:09

US3672187

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
User entered '6 Apr 2021 10:07'	System	06 Apr 2021 14:13:09

US3672187

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:22:10

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:00:39
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:54:12
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 18:33:56

US3672187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:10

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:54:40
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User closed query 'Per DM CLR: RQ: Response noted, however, please update the AE term to include "WORSENING" as appropriate.' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 16:11:19
Query 'Per DM CLR: RQ: Response noted, however, please update the AE term to include "WORSENING" as appropriate.' answered with 'different therefore listed seperate' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 18:43:19
User opened query 'Per DM CLR: RQ: Response noted, however, please update the AE term to include "WORSENING" as appropriate.' (Site from DM).	(b) (4), (b) (6)	28 Nov 2020 14:41:59
User closed query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of HYPERTENSION. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 17:57:05
Query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of HYPERTENSION. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.' answered with 'worsening of subject's ongoing medical history' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 15:02:06
User opened query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of HYPERTENSION. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 11:58:29
User coded data point as SOC: Investigations, HLGT: Cardiac and vascular investigations (excl enzyme tests), HLT: Vascular tests NEC (incl blood pressure), PT: Blood pressure diastolic increased, LLT: Diastolic blood pressure increased - version MedDRA\23.0.	Coder Import (b) (4)	28 Sep 2020 18:36:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	28 Sep 2020 18:36:48
Data point term sent to Coder	System	28 Sep 2020 18:35:35

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:10

[Adverse event](#)

Audit	User	Time (GMT)
User entered 'elevated diastolic blood pressure'	(b) (4), (b) (6)	28 Sep 2020 18:34:59

US3672187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:10

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:54:42
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 18:34:59

US3672187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:10

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:55:22
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 18:34:59

US3672187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:10

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:55:24
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 18:34:59

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:54:52
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered '21 Sep 2020'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:34:59

US3672187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:10

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:55:30
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	(b) (4)	28 Sep 2020 18:35:11
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	28 Sep 2020 18:35:11
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	28 Sep 2020 18:34:59
User entered '10:20'	(b) (4), (b) (6)	28 Sep 2020 18:34:59

US3672187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:10

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 18:35:11
User entered '21 Sep 2020 10:20'	System	28 Sep 2020 18:34:59

US3672187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:10

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:43:24
User closed query 'AE end date is 17OCT220. please verify and update accordingly' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 18:43:13
Query 'AE end date is 17OCT220. please verify and update accordingly' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 16:32:06
Signature has been broken.	(b) (4), (b) (6)	21 Apr 2021 16:31:48
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Apr 2021 16:31:48
User opened query 'AE end date is 17OCT220. please verify and update accordingly' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 13:55:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 18:34:59

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:10

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:43:39
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 16:31:48
Signature has been broken.	(b) (4), (b) (6)	21 Apr 2021 16:31:48
User entered '17 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Apr 2021 16:31:48
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:55:31
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:34:59

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:55:34
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 18:34:59

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:10

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 18:34:59

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:10

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:55:35
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6)	28 Sep 2020 18:34:59

US3672187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:10

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:56:37
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 18:34:59

US3672187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:10

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:56:35
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered '0'	(b) (4), (b) (6)	28 Sep 2020 18:34:59

US3672187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:10

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:56:46
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered '0'	(b) (4), (b) (6)	28 Sep 2020 18:34:59

US3672187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:10

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:57:08
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered '0'	(b) (4), (b) (6)	28 Sep 2020 18:34:59

US3672187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:10

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:57:10
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 18:34:59

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:10

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:57:11
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 18:34:59

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:10

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:57:12
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 18:34:59

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:10

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:57:15
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 18:34:59

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:57:16
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered '0'	(b) (4), (b) (6)	28 Sep 2020 18:34:59

US3672187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:10

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:55:47
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered '0'	(b) (4), (b) (6)	28 Sep 2020 18:34:59

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:10

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:55:45
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered '0'	(b) (4), (b) (6)	28 Sep 2020 18:34:59

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:10

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:55:42
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	28 Sep 2020 18:34:59

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:10

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:55:40
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:34:59

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:10

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:55:37
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User closed query 'Per CDM: The reason provided for study treatment not given on Exposure (V2D29) page is 'ELEVATED DIASTOLIC BLOOD PRESSURE (GRADE 3)' however, 'none' is recorded here. Please confirm the 'Action taken with investigational product' again and update it appropriately or else clarify. Thank you. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 09:53:07
Query 'Per CDM: The reason provided for study treatment not given on Exposure (V2D29) page is 'ELEVATED DIASTOLIC BLOOD PRESSURE (GRADE 3)' however, 'none' is recorded here. Please confirm the 'Action taken with investigational product' again and update it appropriately or else clarify. Thank you. ' answered with 'corrected: investigational product withdrawn' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 14:59:39
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Oct 2020 14:57:38
User opened query 'Per CDM: The reason provided for study treatment not given on Exposure (V2D29) page is 'ELEVATED DIASTOLIC BLOOD PRESSURE (GRADE 3)' however, 'none' is recorded here. Please confirm the 'Action taken with investigational product' again and update it appropriately or else clarify. Thank you. ' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 05:18:27
User entered 'None (NONE)'	(b) (4), (b) (6)	28 Sep 2020 18:34:59

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:10

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:55:49
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User closed query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #2 recorded that matches this AE during this timeframe. Please review and update this field.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 07:55:48
Query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #2 recorded that matches this AE during this timeframe. Please review and update this field.' answered with 'corrected due to conmed taken' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 14:59:16
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	27 Oct 2020 14:57:59
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	27 Oct 2020 14:57:52
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Oct 2020 14:57:52
User opened query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #2 recorded that matches this AE during this timeframe. Please review and update this field.' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 11:58:36
User entered '1'	(b) (4), (b) (6)	28 Sep 2020 18:34:59

US3672187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:10

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:55:53
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Oct 2020 14:57:59
User entered '0'	(b) (4), (b) (6)	28 Sep 2020 18:34:59

US3672187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:10

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:55:51
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered '0'	(b) (4), (b) (6)	28 Sep 2020 18:34:59

US3672187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:10

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:44:07
User closed query 'Per source, AE recovered/resolved. Please verify and update accordingly' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 18:43:51
Query 'Per source, AE recovered/resolved. Please verify and update accordingly' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 16:32:22
Signature has been broken.	(b) (4), (b) (6)	21 Apr 2021 16:31:48
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Apr 2021 16:31:48
User opened query 'Per source, AE recovered/resolved. Please verify and update accordingly' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 13:56:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	28 Sep 2020 18:34:59

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Folder: Adverse Events

Form: Adverse Events (1)

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:56:23
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 18:34:59

US3672187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:10

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:56:24
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 18:34:59

US3672187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:10

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	28 Sep 2020 18:34:59

US3672187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:10

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	28 Sep 2020 18:34:59

US3672187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:10

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 15:03:32
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:27:55
User entered	(b) (4)	16 Mar 2021 14:38:41
'USA-US116-2021-mRNA-1273-P301000009'	System	16 Mar 2021 14:38:41
User entered 'New'	(b) (4), (b) (6)	16 Mar 2021 14:38:41

US3672187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:10

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:27:55
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Lower respiratory tract and lung infections, PT: Pneumonia, LLT: Pneumonia - version MedDRA\\23.0.	Coder Import (b) (4)	16 Mar 2021 00:49:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	16 Mar 2021 00:49:45
Data point term sent to Coder	System	15 Mar 2021 11:56:12
User entered 'pneumonia right lung'	(b) (4), (b) (6)	15 Mar 2021 11:55:52

US3672187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:10

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:27:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 11:55:52

US3672187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:10

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:27:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 11:55:52

US3672187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:10

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:27:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 11:55:52

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:27:55
User entered '6 Mar 2021'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 11:55:52

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:27:55
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	
Query 'Data is required. Please provide.' answered with 'unknown' (Site from System).	(b) (4), (b) (6)	16 Mar 2021 12:14:17
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	15 Mar 2021 11:56:05
User entered empty.	System	15 Mar 2021 11:55:52
	(b) (4), (b) (6)	15 Mar 2021 11:55:52

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:10

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Mar 2021 11:55:52

US3672187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:10

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:27:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 11:55:52

US3672187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:10

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:27:55
User entered '9 Mar 2021'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 11:55:52

US3672187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:27:55
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	
Query 'Data is required. Please provide.' answered with 'unknown' (Site from System).	(b) (4), (b) (6)	16 Mar 2021 12:14:21
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	15 Mar 2021 11:56:07
User entered empty.	System	15 Mar 2021 11:55:52
	(b) (4), (b) (6)	15 Mar 2021 11:55:52

US3672187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:10

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Mar 2021 11:55:52

US3672187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:10

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:09:07
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:27:55
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6)	15 Mar 2021 11:55:52

US3672187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:10

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:09:09
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:27:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Mar 2021 11:55:52

US3672187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:10

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:09:11
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:27:55
User entered '0'	(b) (4), (b) (6)	15 Mar 2021 11:55:52

US3672187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:10

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:09:12
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:27:55
User entered '0'	(b) (4), (b) (6)	15 Mar 2021 11:55:52

US3672187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:10

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:09:13
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:27:55
User entered 'I'	(b) (4), (b) (6)	15 Mar 2021 11:55:52

US3672187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:10

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:09:15
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:27:55
User entered '6 Mar 2021'	(b) (4), (b) (6)	15 Mar 2021 11:55:52

US3672187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:10

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:09:17
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:27:55
User entered '9 Mar 2021'	(b) (4), (b) (6)	15 Mar 2021 11:55:52

US3672187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:10

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:10:02
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:27:55
User entered 'No (N)'	(b) (4), (b) (6)	15 Mar 2021 11:55:52

US3672187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:10

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:10:04
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:27:55
User entered empty.	(b) (4), (b) (6)	15 Mar 2021 11:55:52

US3672187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:10:06
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:27:55
User entered '0'	(b) (4), (b) (6)	15 Mar 2021 11:55:52

US3672187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:10

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:10:08
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:27:55
User entered '0'	(b) (4), (b) (6)	15 Mar 2021 11:55:52

US3672187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:10

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:10:10
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:27:55
User entered '0'	(b) (4), (b) (6)	15 Mar 2021 11:55:52

US3672187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:10

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:10:11
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:27:55
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 11:55:52

US3672187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:10

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:10:12
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:27:55
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	15 Mar 2021 11:55:52

US3672187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:10

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:10:14
User signature succeeded.	Cynthia Strout (b) (4)	12 Apr 2021 20:43:54
User closed query 'PV Query: As the last dose of mRNA 1273 was given on 05 Mar 2021 (prior to event), please update the action taken from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 15:03:36
Query 'PV Query: As the last dose of mRNA 1273 was given on 05 Mar 2021 (prior to event), please update the action taken from none to not applicable.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 17:47:13
Signature has been broken.	(b) (4), (b) (6)	09 Apr 2021 17:43:54
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 17:43:54
User opened query 'PV Query: As the last dose of mRNA 1273 was given on 05 Mar 2021 (prior to event), please update the action taken from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	22 Mar 2021 15:31:59
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:27:55
User entered 'None (NONE)'	(b) (4), (b) (6)	15 Mar 2021 11:55:52

US3672187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:10

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:10:19
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:27:55
User entered '0'	(b) (4), (b) (6)	15 Mar 2021 11:55:52

US3672187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:10

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:10:21
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:27:55
User entered 'I'	(b) (4), (b) (6)	15 Mar 2021 11:55:52

US3672187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:10

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:10:23
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:27:55
User entered '0'	(b) (4), (b) (6)	15 Mar 2021 11:55:52

US3672187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:10

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:10:25
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:27:55
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	15 Mar 2021 11:55:52

US3672187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:10

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:27:55
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 11:55:52

US3672187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:10

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:10:35
User opened query 'PV Query: A negative COVID-19 test was reported. Please specify the date and type of test performed if known.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 16:55:23
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. Please keep query open until records are received.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 16:55:15
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	14 Apr 2021 16:03:36
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	14 Apr 2021 16:03:31
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'Records requested' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 19:39:13
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' answered with 'Negative COVID results' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 19:38:40

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:10

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	22 Mar 2021 15:31:42
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	22 Mar 2021 15:31:32
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:27:55
User entered 'At patient's OL D36 TC it was mentioned patient had recently spent time in the hospital at the VA for pneumonia in the right lung. Patient was treated with Cefdinir and released after a full recovery.'	(b) (4), (b) (6)	15 Mar 2021 11:55:52

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:10

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	15 Mar 2021 11:55:52

US3672187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:10

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	15 Mar 2021 11:55:52

US3672187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:10

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	15 Mar 2021 11:55:52

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:22:10

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:00:39
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:11:06
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Sep 2020 18:32:56
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 12:51:07

US3672187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:22:10

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:11:44
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Sep 2020 18:34:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Sep 2020 18:34:38
Data point term sent to Coder	System	28 Sep 2020 18:33:31
User entered 'asprin'	(b) (4), (b) (6)	28 Sep 2020 18:33:26

US3672187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:22:10

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:11:44
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 18:33:26

US3672187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:22:10

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:11:44
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered 'cardiac prophylaxis'	(b) (4), (b) (6)	28 Sep 2020 18:33:26

US3672187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:22:10

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:11:44
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered '81'	(b) (4), (b) (6)	28 Sep 2020 18:33:26

US3672187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:22:10

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:11:44
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered 'mg (mg)'	(b) (4), (b) (6)	28 Sep 2020 18:33:26

US3672187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:22:10

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:11:44
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:33:26

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:22:10

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:11:44
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered 'as needed (PRN)'	(b) (4), (b) (6)	28 Sep 2020 18:33:26

US3672187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:22:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:11:44
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:33:26

US3672187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:22:10

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:11:44
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	28 Sep 2020 18:33:26

US3672187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:22:10

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:11:44
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:33:26

US3672187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:11:44
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered 'un UNK 2018'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:33:26

US3672187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:22:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:11:44
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered '0'	(b) (4), (b) (6)	28 Sep 2020 18:33:26

US3672187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:22:10

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:11:44
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 18:33:26

US3672187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:11:44
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 18:33:26

US3672187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:22:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:11:44
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:33:26

US3672187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:22:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 18:33:26

US3672187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:22:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 18:33:26

US3672187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:22:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 18:33:26

US3672187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:22:10

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:11:44
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN, PRODUCTSYNONYM: LIPITOR [ATORVASTATIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Sep 2020 18:35:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Sep 2020 18:35:42
Data point term sent to Coder	System	28 Sep 2020 18:34:31
User entered 'lipitor'	(b) (4), (b) (6)	28 Sep 2020 18:33:41

US3672187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:22:10

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:11:44
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 18:33:41

US3672187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:22:10

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:11:44
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered 'hypertension'	(b) (4), (b) (6)	28 Sep 2020 18:33:41

US3672187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:22:10

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:11:44
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered '10'	(b) (4), (b) (6)	28 Sep 2020 18:33:41

US3672187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:22:10

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:11:44
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered 'mg (mg)'	(b) (4), (b) (6)	28 Sep 2020 18:33:41

US3672187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:22:10

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:11:44
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 18:33:41

US3672187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:22:10

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:11:44
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered 'once daily (QD)'	(b) (4), (b) (6)	28 Sep 2020 18:33:41

US3672187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:22:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:11:44
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 18:33:41

US3672187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:22:10

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:11:44
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	28 Sep 2020 18:33:41

US3672187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:22:10

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:11:44
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:33:41

US3672187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:11:44
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered '26 Sep 2020'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:33:41

US3672187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:22:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:11:44
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered '0'	(b) (4), (b) (6)	28 Sep 2020 18:33:41

US3672187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:22:10

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:11:44
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 18:33:41

US3672187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:11:44
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 18:33:41

US3672187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:22:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:11:44
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:33:41

US3672187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:22:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 18:33:41

US3672187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:22:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 18:33:41

US3672187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:22:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Sep 2020 18:33:41

US3672187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:22:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:12:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:11:44
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:40:12
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFDINIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Mar 2021 14:20:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Mar 2021 14:20:56
Data point term sent to Coder	System	15 Mar 2021 12:27:35
User entered 'cefdinir'	(b) (4), (b) (6)	15 Mar 2021 12:26:56

US3672187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:22:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:12:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:11:44
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:40:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 12:26:56

US3672187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:22:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:12:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:11:44
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:40:12
User entered 'pneumonia right lung'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 12:26:56

US3672187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:22:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:12:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:11:44
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:40:12
User entered '300'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 12:26:56

US3672187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:22:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:12:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:11:44
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:40:12
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 12:26:56

US3672187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:22:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:12:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:11:44
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:40:12
User entered empty.	(b) (4), (b) (6)	15 Mar 2021 12:26:56

US3672187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:22:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:12:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:11:44
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:40:12
User entered 'twice daily (BID)'	(b) (4), (b) (6)	15 Mar 2021 12:26:56

US3672187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:22:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:12:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:11:44
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:40:12
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 12:26:56

US3672187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:22:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:12:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:11:44
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:40:12
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	15 Mar 2021 12:26:56

US3672187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:22:10

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:12:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:11:44
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:40:12
User entered empty.	(b) (4), (b) (6)	15 Mar 2021 12:26:56

US3672187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:12:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:11:44
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:40:12
User entered '6 Mar 2021'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 12:26:56

US3672187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:22:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:12:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:11:44
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:40:12
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 12:26:56

US3672187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:22:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:12:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:11:44
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:40:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 12:26:56

US3672187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:12:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:11:44
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:40:12
User entered '7 Mar 2021'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 12:26:56

US3672187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:22:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:12:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:11:44
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:40:12
User entered 'No (N)'	(b) (4), (b) (6)	15 Mar 2021 12:26:56

US3672187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:22:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:12:06
User entered '2'	System	15 Mar 2021 12:26:56

US3672187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:22:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:12:06
User entered '1'	System	15 Mar 2021 12:26:56

US3672187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:22:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:12:06
User entered '804 (804)'	System	15 Mar 2021 12:26:56

US3672187

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:22:10

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:11:47
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:40:12
User entered 'No (N)'	(b) (4), (b) (6)	08 Mar 2021 21:40:22

US3672187

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:22:10

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:27:03
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:11:57
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered '21 Sep 2020'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:03:35

US3672187

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:22:10

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:27:03
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:11:57
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
User entered 'AE (specify) (ADVERSE EVENT)'	(b) (4), (b) (6)	09 Dec 2020 21:03:35

US3672187

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:22:10

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 03:27:03
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:11:57
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:59:20
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 10:58:07
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 14:33:55
User entered 'AE #1' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 14:33:47
User opened query 'Per CDM: Per sponsor review, please consider updating specify field to include only AE, number sign, and number. (i.e. AE #1). Thank you. ' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 14:13:45
User closed query 'Per CDM:Kindly consider to remove all details and update only the AE log line number.Thank you.' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 11:22:02
Query 'Per CDM:Kindly consider to remove all details and update only the AE log line number.Thank you.' answered with 'done' (Site from DM).	Patty Howenstine (b) (4)	25 Feb 2021 17:23:45
User entered 'AE log #1' reason for change: Data Entry Error	Patty Howenstine (b) (4)	25 Feb 2021 17:23:26
User opened query 'Per CDM:Kindly consider to remove all details and update only the AE log line number.Thank you.' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 02:48:11
User closed query 'Per CDM: Please record AE record number instead of details ' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 02:43:41
Query 'Per CDM: Please record AE record number instead of details ' answered with 'recorded' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 21:32:06
User opened query 'Per CDM: Please record AE record number instead of details ' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 12:50:50

US3672187

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:22:10

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

Audit	User	Time (GMT)
User closed query 'Primary reason for dosing discontinuation is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is missing. Please provide.' (Site from System).	System	09 Dec 2020 21:03:56
User entered 'ELEVATED DIASTOLIC BLOOD PRESSURE (GRADE 3)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Dec 2020 21:03:56
User opened query 'Primary reason for dosing discontinuation is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is missing. Please provide.' (Site from System).	System	09 Dec 2020 21:03:35
User entered empty.	(b) (4), (b) (6)	09 Dec 2020 21:03:35

US3672187

Folder: SAE USA-US116-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:10

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:53:35
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 14:39:04
User entered 'USA-US116-2021-MRNA-1273-P301000009'	System	16 Mar 2021 14:38:41

US3672187

Folder: SAE USA-US116-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:10

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:53:36
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 14:39:04
User entered 'Yes (Y)'	System	16 Mar 2021 14:38:41

US3672187

Folder: SAE USA-US116-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:10

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:53:43
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 14:39:04
User entered 'No (N)'	System	16 Mar 2021 14:38:41

US3672187

Folder: SAE USA-US116-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:10

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:53:47
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 14:39:04
User entered 'No (N)'	System	16 Mar 2021 14:38:41

US3672187

Folder: SAE USA-US116-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:10

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:53:49
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 14:39:04
User entered 'Yes (Y)'	System	16 Mar 2021 14:38:41

US3672187

Folder: SAE USA-US116-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:53:51
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 14:39:04
User entered 'No (N)'	System	16 Mar 2021 14:38:41

US3672187

Folder: SAE USA-US116-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:10

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:53:52
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 14:39:04
User entered 'No (N)'	System	16 Mar 2021 14:38:41

US3672187

Folder: SAE USA-US116-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:10

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:53:53
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 14:39:04
User entered 'No (N)'	System	16 Mar 2021 14:38:41

US3672187

Folder: SAE USA-US116-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:10

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:53:54
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 14:39:04
User entered 'Cynthia'	System	16 Mar 2021 14:38:41

US3672187

Folder: SAE USA-US116-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:10

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:53:56
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 14:39:04
User entered 'Strout'	System	16 Mar 2021 14:38:41

US3672187

Folder: SAE USA-US116-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:10

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	22 Apr 2021 18:35:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:44:59
User closed query 'Please change to the most recent address.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 18:44:40
Query 'Please change to the most recent address.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 16:33:22
Un-reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 16:33:06
Signature has been broken.	(b) (4), (b) (6)	21 Apr 2021 16:33:06
User entered '4920 O Hear AVE Suite 101' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Apr 2021 16:33:06
User opened query 'Please change to the most recent address.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 13:47:45
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 14:39:04
User entered '1156 Bowman Road'	System	16 Mar 2021 14:38:41

US3672187

Folder: SAE USA-US116-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:10

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:44:59
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 14:39:04
User entered 'Mount Pleasant'	System	16 Mar 2021 14:38:41

US3672187

Folder: SAE USA-US116-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:10

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	22 Apr 2021 18:35:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:44:59
User entered 'SC'	(b) (4), (b) (6)	21 Apr 2021 16:33:06

US3672187

Folder: SAE USA-US116-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:10

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:44:59
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 14:39:04
User entered '29464'	System	16 Mar 2021 14:38:41

US3672187

Folder: SAE USA-US116-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:10

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:53:58
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:03:49
User entered 'US'	System	16 Mar 2021 14:39:19

US3672187

Folder: SAE USA-US116-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:10

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	12 Apr 2021 15:04:05
User entered '1'	System	16 Mar 2021 14:39:19

US3672187

Folder: SAE USA-US116-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:10

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:53:35
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 14:39:04
User entered 'USA-US116-2021-MRNA-1273-P301000009'	System	16 Mar 2021 14:38:41

US3672187

Folder: SAE USA-US116-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:10

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:53:36
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 14:39:04
User entered 'Yes (Y)'	System	16 Mar 2021 14:38:41

US3672187

Folder: SAE USA-US116-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:10

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:53:43
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 14:39:04
User entered 'No (N)'	System	16 Mar 2021 14:38:41

US3672187

Folder: SAE USA-US116-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:10

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:53:47
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 14:39:04
User entered 'No (N)'	System	16 Mar 2021 14:38:41

US3672187

Folder: SAE USA-US116-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:10

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:53:49
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 14:39:04
User entered 'Yes (Y)'	System	16 Mar 2021 14:38:41

US3672187

Folder: SAE USA-US116-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:53:51
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 14:39:04
User entered 'No (N)'	System	16 Mar 2021 14:38:41

US3672187

Folder: SAE USA-US116-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:10

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:53:52
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 14:39:04
User entered 'No (N)'	System	16 Mar 2021 14:38:41

US3672187

Folder: SAE USA-US116-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:10

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:53:53
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 14:39:04
User entered 'No (N)'	System	16 Mar 2021 14:38:41

US3672187

Folder: SAE USA-US116-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:10

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:53:54
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 14:39:04
User entered 'Cynthia'	System	16 Mar 2021 14:38:41

US3672187

Folder: SAE USA-US116-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:10

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:53:56
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 14:39:04
User entered 'Strout'	System	16 Mar 2021 14:38:41

US3672187

Folder: SAE USA-US116-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:10

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	22 Apr 2021 18:35:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:44:59
User closed query 'Please change to the most recent address.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 18:44:40
Query 'Please change to the most recent address.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 16:33:22
Un-reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 16:33:06
Signature has been broken.	(b) (4), (b) (6)	21 Apr 2021 16:33:06
User entered '4920 O Hear AVE Suite 101' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Apr 2021 16:33:06
User opened query 'Please change to the most recent address.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 13:47:45
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 14:39:04
User entered '1156 Bowman Road'	System	16 Mar 2021 14:38:41

US3672187

Folder: SAE USA-US116-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:10

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:44:59
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 14:39:04
User entered 'Mount Pleasant'	System	16 Mar 2021 14:38:41

US3672187

Folder: SAE USA-US116-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:10

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	22 Apr 2021 18:35:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:44:59
User entered 'SC'	(b) (4), (b) (6)	21 Apr 2021 16:33:06

US3672187

Folder: SAE USA-US116-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:10

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:44:59
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 14:39:04
User entered '29464'	System	16 Mar 2021 14:38:41

US3672187

Folder: SAE USA-US116-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:10

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:53:58
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:03:49
User entered 'US'	System	16 Mar 2021 14:39:19

US3672187

Folder: SAE USA-US116-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:10

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	12 Apr 2021 15:04:05
User entered '1'	System	16 Mar 2021 14:39:19

US3672187

Folder: SAE USA-US116-2021-MRNA-1273-P301000009

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:22:10

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:54:00
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
User entered '16/Mar/2021 10:39'	(b) (4) System	16 Mar 2021 14:39:19

US3672187

Folder: SAE USA-US116-2021-MRNA-1273-P301000009

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:22:10

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:54:02
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 15:03:49
User entered 'I'	(b) (4), (b) (6)	16 Mar 2021 14:39:19

US3672187

Folder: SAE USA-US116-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:10

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:53:35
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 14:39:04
User entered 'USA-US116-2021-MRNA-1273-P301000009'	System	16 Mar 2021 14:38:41

US3672187

Folder: SAE USA-US116-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:10

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:53:36
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 14:39:04
User entered 'Yes (Y)'	System	16 Mar 2021 14:38:41

US3672187

Folder: SAE USA-US116-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:10

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:53:43
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 14:39:04
User entered 'No (N)'	System	16 Mar 2021 14:38:41

US3672187

Folder: SAE USA-US116-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:10

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:53:47
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 14:39:04
User entered 'No (N)'	System	16 Mar 2021 14:38:41

US3672187

Folder: SAE USA-US116-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:10

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:53:49
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 14:39:04
User entered 'Yes (Y)'	System	16 Mar 2021 14:38:41

US3672187

Folder: SAE USA-US116-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:53:51
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 14:39:04
User entered 'No (N)'	System	16 Mar 2021 14:38:41

US3672187

Folder: SAE USA-US116-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:10

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:53:52
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 14:39:04
User entered 'No (N)'	System	16 Mar 2021 14:38:41

US3672187

Folder: SAE USA-US116-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:10

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:53:53
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 14:39:04
User entered 'No (N)'	System	16 Mar 2021 14:38:41

US3672187

Folder: SAE USA-US116-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:10

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:53:54
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 14:39:04
User entered 'Cynthia'	System	16 Mar 2021 14:38:41

US3672187

Folder: SAE USA-US116-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:10

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:53:56
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 14:39:04
User entered 'Strout'	System	16 Mar 2021 14:38:41

US3672187

Folder: SAE USA-US116-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:10

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	22 Apr 2021 18:35:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:44:59
User closed query 'Please change to the most recent address.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 18:44:40
Query 'Please change to the most recent address.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 16:33:22
Un-reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 16:33:06
Signature has been broken.	(b) (4), (b) (6)	21 Apr 2021 16:33:06
User entered '4920 O Hear AVE Suite 101' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Apr 2021 16:33:06
User opened query 'Please change to the most recent address.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 13:47:45
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 14:39:04
User entered '1156 Bowman Road'	System	16 Mar 2021 14:38:41

US3672187

Folder: SAE USA-US116-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:10

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:44:59
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 14:39:04
User entered 'Mount Pleasant'	System	16 Mar 2021 14:38:41

US3672187

Folder: SAE USA-US116-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:10

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	22 Apr 2021 18:35:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:44:59
User entered 'SC'	(b) (4), (b) (6)	21 Apr 2021 16:33:06

US3672187

Folder: SAE USA-US116-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:10

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:44:59
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 14:39:04
User entered '29464'	System	16 Mar 2021 14:38:41

US3672187

Folder: SAE USA-US116-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:10

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:53:58
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:03:49
User entered 'US'	System	16 Mar 2021 14:39:19

US3672187

Folder: SAE USA-US116-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:10

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	12 Apr 2021 15:04:05
User entered '1'	System	16 Mar 2021 14:39:19

US3672187

Folder: SAE USA-US116-2021-MRNA-1273-P301000009

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:22:10

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:54:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
User entered '12/Apr/2021 10:03'	(b) (4) System	12 Apr 2021 15:04:05

US3672187

Folder: SAE USA-US116-2021-MRNA-1273-P301000009

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:22:10

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:54:09
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:08:27
User entered 'I'	(b) (4), (b) (6)	12 Apr 2021 15:04:05