

US3172467 (Prod: Suncoast Research Group LLC - ERN-PPDS)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:06:47

All time stamps listed in this document are displayed in GMT

US3172467

Form: Participant Creation

Data signed: (b) (4) 17 Feb 2021 13:52:13

Generated On: 11 Aug 2021 22:06:47

Participant ID

US3172467

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

US3172467

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 13:52:13

Generated On: 11 Aug 2021 22:06:47

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

Visit date (dd MMM yyyy)	21 OCT 2020
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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	SCRN
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US3172467

Folder: Screening

Form: Demographics

Data signed: (b) (4) 17 Feb 2021 13:52:13

Generated On: 11 Aug 2021 22:06:47

Date of Birth (MMM yyyy)	(b) (6) 1965
Age	55
Age Units	YEARS
Age (Derived)	55
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input 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

US3172467

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 17 Feb 2021 13:52:13

Generated On: 11 Aug 2021 22:06:47

Date of Informed Consent (dd MMM yyyy) 21 OCT 2020

Month and Year of Informed Consent (derived) OCT 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) 17 Feb 2021 13:52:13

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 17 Feb 2021 13:52:13

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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) 17 Feb 2021 13:52:13

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Condition	LEFT EYE GLAUCOMA
Start date (dd MMM yyyy)	UN UNK 1998
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 1998
Start Year (derived)	1998
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 17 Feb 2021 13:52:13

Generated On: 11 Aug 2021 22:06:47

Condition	PRESBYOPIA
Start date (dd MMM yyyy)	UN UNK 2010
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 2010
Start Year (derived)	2010
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 17 Feb 2021 13:52:13

Generated On: 11 Aug 2021 22:06:47

Condition	OCCASIONAL NOSE BLEEDS
Start date (dd MMM yyyy)	UN UNK 2015
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 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

US3172467

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 17 Feb 2021 13:52:13

Generated On: 11 Aug 2021 22:06:47

Condition	RIGHT SCAPHOIDE FRACTURE (RIGHT HAND)
Start date (dd MMM yyyy)	UN UNK 2011
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2011
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2011
Start Year (derived)	2011
Stop Month and Year (derived)	JAN 2011
Stop Year (derived)	2011

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 17 Feb 2021 13:52:13

Generated On: 11 Aug 2021 22:06:47

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	21 OCT 2020
Time of assessment (00:00-23:59)	14:15 (24 HR)
Vital Signs Date and Time (derived)	21 OCT 2020 14:15
Height (xxx.x)	176.0 cm
Weight (xxx.x)	86.5 kg
BMI (xxx.x)	27.92485 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 13:52:13

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Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 17 Feb 2021 13:52:13

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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) 17 Feb 2021 13:52:13

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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)	True
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	False
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 13:52:14

Generated On: 11 Aug 2021 22:06:47

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 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	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 17 Feb 2021 13:52:14

Generated On: 11 Aug 2021 22:06:47

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

What was the participant's randomization number? 117728

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) 17 Feb 2021 13:52:14

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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) 17 Feb 2021 13:52:14

Generated On: 11 Aug 2021 22:06:47

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)	21 OCT 2020
Time of assessment (00:00-23:59)	14:15 (24 HR)
Vital Signs Date and Time (derived)	21 OCT 2020 14:15
Temperature (xxx.x)	37.1 C
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)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	106 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 17 Feb 2021 13:52:14

Generated On: 11 Aug 2021 22:06:47

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	21 OCT 2020
Time of assessment (00:00-23:59)	16:43 (24 HR)
Vital Signs Date and Time (derived)	21 OCT 2020 16:43
Temperature (xxx.x)	37.0 C
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
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)	102 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	64 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 13:52:13

Generated On: 11 Aug 2021 22:06:47

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 OCT 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) 17 Feb 2021 13:52:13

Generated On: 11 Aug 2021 22:06:47

Was study treatment given? Yes ☒ No ☐

If No, reason not given Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 21 OCT 2020

What was the treatment time? (00:00-23:59) 16:13 (24 HR)

Treatment Date and Time (derived) 21 OCT 2020 16:13

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) 17 Feb 2021 13:52:13

Generated On: 11 Aug 2021 22:06:47

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

Collection date (dd MMM yyyy)	21 OCT 2020
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Collection time (00:00-23:59)	15:39 (24 HR)
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Collection date and time (derived)	21 OCT 2020 15:39
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US3172467

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 17 Feb 2021 13:52:13

Generated On: 11 Aug 2021 22:06:47

Collection date (dd MMM yyyy)			21 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:42	21 OCT 2020 15:42
Nasopharyngeal Swab 2	No		

US3172467

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:52:13

Generated On: 11 Aug 2021 22:06:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 OCT 2020 16:45

PC Open Date & Time

21 OCT 2020 16:33

PC Close Date & Time

21 OCT 2020 19:03

US3172467

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.5 °F

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

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

PC Time Stamp	21 OCT 2020 20:01
PC Open Date & Time	21 OCT 2020 19:58
PC Close Date & Time	22 OCT 2020 11:59

US3172467

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °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

22 OCT 2020 13:09

PC Open Date & Time

22 OCT 2020 12:00

PC Close Date & Time

23 OCT 2020 11:59

US3172467

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 OCT 2020 12:01

PC Open Date & Time

23 OCT 2020 12:00

PC Close Date & Time

24 OCT 2020 11:59

US3172467

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:06:47

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

96.0 °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 OCT 2020 12:51

PC Open Date & Time

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59

US3172467

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:06:47

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

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

25 OCT 2020 16:24

PC Open Date & Time

25 OCT 2020 12:00

PC Close Date & Time

26 OCT 2020 11:59

US3172467

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:06:47

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

96.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 OCT 2020 12:00

PC Open Date & Time

26 OCT 2020 12:00

PC Close Date & Time

27 OCT 2020 11:59

US3172467

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 OCT 2020 13:42

PC Open Date & Time

27 OCT 2020 12:00

PC Close Date & Time

28 OCT 2020 11:59

US3172467

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

21 OCT 2020 16:46

PC Open Date & Time

21 OCT 2020 16:33

PC Close Date & Time

21 OCT 2020 19:03

US3172467

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

21 OCT 2020 20:01

PC Open Date & Time

21 OCT 2020 19:58

PC Close Date & Time

22 OCT 2020 11:59

US3172467

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

22 OCT 2020 13:09

PC Open Date & Time

22 OCT 2020 12:00

PC Close Date & Time

23 OCT 2020 11:59

US3172467

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

23 OCT 2020 12:01

PC Open Date & Time

23 OCT 2020 12:00

PC Close Date & Time

24 OCT 2020 11:59

US3172467

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

24 OCT 2020 12:51

PC Open Date & Time

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59

US3172467

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

25 OCT 2020 16:25

PC Open Date & Time

25 OCT 2020 12:00

PC Close Date & Time

26 OCT 2020 11:59

US3172467

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

26 OCT 2020 12:01

PC Open Date & Time

26 OCT 2020 12:00

PC Close Date & Time

27 OCT 2020 11:59

US3172467

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

27 OCT 2020 13:42

PC Open Date & Time

27 OCT 2020 12:00

PC Close Date & Time

28 OCT 2020 11:59

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:06:47

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 ☐

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:06:47

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

No ☒

Yes ☐

PC Time stamp	21 OCT 2020 16:47
PC Open Date & Time	21 OCT 2020 16:33
PC Close Date & Time	21 OCT 2020 19:03

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:06:47

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 ☐

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:06:47

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

No ☒

Yes ☐

PC Time stamp	21 OCT 2020 20:02
PC Open Date & Time	21 OCT 2020 19:58
PC Close Date & Time	22 OCT 2020 11:59

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:06:47

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 ☒

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:06:47

Yes <input type="checkbox"/>	
PC Time stamp	22 OCT 2020 13:10
PC Open Date & Time	22 OCT 2020 12:00
PC Close Date & Time	23 OCT 2020 11:59

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:06:47

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 ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:06:47

Yes <input type="checkbox"/>	
PC Time stamp	23 OCT 2020 12:02
PC Open Date & Time	23 OCT 2020 12:00
PC Close Date & Time	24 OCT 2020 11:59

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:06:47

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 ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:06:47

Yes <input type="checkbox"/>	
PC Time stamp	24 OCT 2020 12:52
PC Open Date & Time	24 OCT 2020 12:00
PC Close Date & Time	25 OCT 2020 11:59

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:06:47

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 ☒

PRODUCTION RELEASE (v12.003

51 of 1477

EAB) (1725)

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:06:47

		Yes <input type="checkbox"/>
PC Time stamp	25 OCT 2020 16:25	
PC Open Date & Time	25 OCT 2020 12:00	
PC Close Date & Time	26 OCT 2020 11:59	

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:06:47

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 ☒

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:06:47

Yes <input type="checkbox"/>	
PC Time stamp	26 OCT 2020 12:01
PC Open Date & Time	26 OCT 2020 12:00
PC Close Date & Time	27 OCT 2020 11:59

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:06:47

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 ☒

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:06:47

Yes <input type="checkbox"/>	
PC Time stamp	27 OCT 2020 13:43
PC Open Date & Time	27 OCT 2020 12:00
PC Close Date & Time	28 OCT 2020 11:59

US3172467

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:52:13

Generated On: 11 Aug 2021 22:06:47

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 30 OCT 2020

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

Comments UNABLE TO CONTACT
SUBJECT. LEFT MESSAGE.

If Contact Not Made, please provide Comments

US3172467

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:52:13

Generated On: 11 Aug 2021 22:06:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172467

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:52:13

Generated On: 11 Aug 2021 22:06:47

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 05 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3172467

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:52:13

Generated On: 11 Aug 2021 22:06:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172467

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:52:13

Generated On: 11 Aug 2021 22:06:47

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 12 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3172467

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:52:13

Generated On: 11 Aug 2021 22:06:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172467

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 13:52:14

Generated On: 11 Aug 2021 22:06:47

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	18 NOV 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

US3172467

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 17 Feb 2021 13:52:14

Generated On: 11 Aug 2021 22:06:47

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)	18 NOV 2020
Time of assessment (00:00-23:59)	11:12 (24 HR)
Vital Signs Date and Time (derived)	18 NOV 2020 11:12
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3172467

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 17 Feb 2021 13:52:14

Generated On: 11 Aug 2021 22:06:47

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	

US3172467

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 13:52:14

Generated On: 11 Aug 2021 22:06:47

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

18 NOV 2020

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

US3172467

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 17 Feb 2021 13:52:14

Generated On: 11 Aug 2021 22:06:47

Was study treatment given? Yes ☐
No ☒

If No, reason not given

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

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

What was the study treatment?

What was the treatment date? (dd MMM yyyy)

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

Treatment Date and Time (derived)

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

What was the frequency of the study treatment dosing?

What was the route of administration for the study treatment?

US3172467

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 17 Feb 2021 13:52:14

Generated On: 11 Aug 2021 22:06:47

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

Collection date (dd MMM yyyy)	18 NOV 2020
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Collection time (00:00-23:59)	13:07 (24 HR)
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Collection date and time (derived)	18 NOV 2020 13:07
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US3172467

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 17 Feb 2021 13:52:14

Generated On: 11 Aug 2021 22:06:47

Collection date (dd MMM yyyy)			18 NOV 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:09	18 NOV 2020 13:09
Nasopharyngeal Swab 2	No		

US3172467

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:52:14

Generated On: 11 Aug 2021 22:06:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172467

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:52:13

Generated On: 11 Aug 2021 22:06:47

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 25 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3172467

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:52:13

Generated On: 11 Aug 2021 22:06:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172467

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:52:13

Generated On: 11 Aug 2021 22:06:47

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 02 DEC 2020

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

Comments

If Contact Not Made, please provide Comments

US3172467

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:52:13

Generated On: 11 Aug 2021 22:06:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172467

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:52:13

Generated On: 11 Aug 2021 22:06:47

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 09 DEC 2020

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

Comments

If Contact Not Made, please provide Comments

US3172467

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:52:13

Generated On: 11 Aug 2021 22:06:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172467

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 13:52:14

Generated On: 11 Aug 2021 22:06:47

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

Visit date (dd MMM yyyy)	16 DEC 2020
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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	VISIT3
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US3172467

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 17 Feb 2021 13:52:14

Generated On: 11 Aug 2021 22:06:47

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	16 DEC 2020
Time of assessment (00:00-23:59)	12:06 (24 HR)
Vital Signs Date and Time (derived)	16 DEC 2020 12:06
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3172467

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 13:52:14

Generated On: 11 Aug 2021 22:06:47

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.

US3172467

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 17 Feb 2021 13:52:14

Generated On: 11 Aug 2021 22:06:47

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

Collection date (dd MMM yyyy)	16 DEC 2020
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Collection time (00:00-23:59)	12:28 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	16 DEC 2020 12:28
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US3172467

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:52:14

Generated On: 11 Aug 2021 22:06:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT	DAY 61
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	21 DEC 2020 18:00:25
Patient Cloud Open Date & Time	18 DEC 2020 00:01
Patient Cloud Close Date & Time	22 DEC 2020 23:59

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	25 DEC 2020 00:06:28
Patient Cloud Open Date & Time	25 DEC 2020 00:01
Patient Cloud Close Date & Time	29 DEC 2020 23:59

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 JAN 2021 12:14:45
Patient Cloud Open Date & Time	01 JAN 2021 00:01
Patient Cloud Close Date & Time	05 JAN 2021 23:59

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

DAY 82

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 JAN 2021 21:23:14

Patient Cloud Open Date & Time

08 JAN 2021 00:01

Patient Cloud Close Date & Time

12 JAN 2021 23:59

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 JAN 2021 21:58:20
Patient Cloud Open Date & Time	15 JAN 2021 00:01
Patient Cloud Close Date & Time	19 JAN 2021 23:59

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

DAY 96

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 JAN 2021 01:38:10

Patient Cloud Open Date & Time

22 JAN 2021 00:01

Patient Cloud Close Date & Time

26 JAN 2021 23:59

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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 <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	29 JAN 2021 19:16:48
Patient Cloud Open Date & Time	29 JAN 2021 00:01
Patient Cloud Close Date & Time	02 FEB 2021 23:59

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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

07 FEB 2021 12:00:49

Patient Cloud Open Date & Time

05 FEB 2021 00:01

Patient Cloud Close Date & Time

09 FEB 2021 23:59

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 FEB 2021 10:31:15

Patient Cloud Open Date & Time

12 FEB 2021 00:01

Patient Cloud Close Date & Time

16 FEB 2021 23:59

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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

21 FEB 2021 12:02:55

Patient Cloud Open Date & Time

19 FEB 2021 00:01

Patient Cloud Close Date & Time

23 FEB 2021 23:59

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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 FEB 2021 12:00:40

Patient Cloud Open Date & Time

26 FEB 2021 00:01

Patient Cloud Close Date & Time

02 MAR 2021 23:59

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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

05 MAR 2021 07:06:13

Patient Cloud Open Date & Time

05 MAR 2021 00:01

Patient Cloud Close Date & Time

09 MAR 2021 23:59

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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

14 MAR 2021 12:32:34

Patient Cloud Open Date & Time

12 MAR 2021 00:01

Patient Cloud Close Date & Time

16 MAR 2021 23:59

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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

20 MAR 2021 18:50:25

Patient Cloud Open Date & Time

19 MAR 2021 00:01

Patient Cloud Close Date & Time

23 MAR 2021 23:59

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 MAR 2021 13:22:25

Patient Cloud Open Date & Time

26 MAR 2021 00:01

Patient Cloud Close Date & Time

30 MAR 2021 23:59

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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

04 APR 2021 12:41:31

Patient Cloud Open Date & Time

02 APR 2021 00:01

Patient Cloud Close Date & Time

06 APR 2021 23:59

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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

09 APR 2021 00:24:56

Patient Cloud Open Date & Time

09 APR 2021 00:01

Patient Cloud Close Date & Time

13 APR 2021 23:59

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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 <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"/>

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

20 APR 2021 23:59

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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

23 APR 2021 06:45:20

Patient Cloud Open Date & Time

23 APR 2021 00:01

Patient Cloud Close Date & Time

27 APR 2021 23:59

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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 <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"/>

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2021 23:59

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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="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"/>

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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 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"/>

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

DAY 222

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

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

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

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

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

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

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

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

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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 <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"/>

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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 <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"/>

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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 <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"/>

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

DAY 250

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

DAY 257

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

DAY 264

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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 <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"/>

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2021 23:59

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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 <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"/>

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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 <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"/>

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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 <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"/>

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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
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Patient Cloud Close Date & Time	17 AUG 2021 23:59
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US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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

[Patient Cloud Close Date & Time](#)

24 AUG 2021 23:59

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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°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 ☐

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

DAY 320

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

DAY 327

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

DAY 334

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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"/>

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

24 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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"/>

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2021 23:59

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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 ☐

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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 <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"/>

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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
Patient Cloud Close Date & Time	19 OCT 2021 23:59

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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

[Patient Cloud Close Date & Time](#)

26 OCT 2021 23:59

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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="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"/>

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

DAY 390

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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"/>

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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"/>

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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"/>

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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 <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"/>

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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 <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"/>

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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"/>

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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"/>

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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"/>

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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 <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"/>

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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 ☐

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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 ☐

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

DAY 495

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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 <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"/>

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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 ☐

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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 <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"/>

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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 ☐

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAR 2022 23:59

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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 ☐

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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 <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"/>

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

19 APR 2022 23:59

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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 <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"/>

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

26 APR 2022 23:59

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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 ☐

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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 ☐

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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 ☐

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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°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 ☐

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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 ☐

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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 ☐

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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"/>

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2022 23:59

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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 <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"/>

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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"/>

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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 <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"/>

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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 ☐

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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 <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"/>

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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 <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"/>

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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 <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"/>

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2022 23:59

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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

[Patient Cloud Close Date & Time](#)

16 AUG 2022 23:59

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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"/>

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2022 23:59

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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 ☐

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 AUG 2022 00:01

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30 AUG 2022 23:59

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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"/>

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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 <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"/>

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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 <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"/>

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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 <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"/>

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

DAY 719

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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

[Patient Cloud Close Date & Time](#)

11 OCT 2022 23:59

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

DAY 726

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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

[Patient Cloud Close Date & Time](#)

18 OCT 2022 23:59

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

DAY 740

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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

[Patient Cloud Close Date & Time](#)

01 NOV 2022 23:59

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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 ☐

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2022 23:59

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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 <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"/>

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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

[Patient Cloud Close Date & Time](#)

15 NOV 2022 23:59

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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"/>

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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

[Patient Cloud Close Date & Time](#)

22 NOV 2022 23:59

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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 <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"/>

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2022 23:59

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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

[Patient Cloud Close Date & Time](#)

06 DEC 2022 23:59

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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

[Patient Cloud Close Date & Time](#)

13 DEC 2022 23:59

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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 <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"/>

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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

[Patient Cloud Close Date & Time](#)

20 DEC 2022 23:59

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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"/>

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 DEC 2022 00:01

[Patient Cloud Close Date & Time](#)

27 DEC 2022 23:59

US3172467

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:06:47

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		28 FEB 2021 12:00:55

US3172467

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:52:13

Generated On: 11 Aug 2021 22:06:47

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 14 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3172467

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:52:13

Generated On: 11 Aug 2021 22:06:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172467

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 14:43:38

Generated On: 11 Aug 2021 22:06:47

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 18 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3172467

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 14:43:32

Generated On: 11 Aug 2021 22:06:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172467

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 22 Apr 2021 16:45:20

Generated On: 11 Aug 2021 22:06:47

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 18 MAR 2021

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

Comments

If Contact Not Made, please provide Comments

US3172467

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 22 Apr 2021 16:45:20

Generated On: 11 Aug 2021 22:06:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172467

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 22 Apr 2021 16:45:20

Generated On: 11 Aug 2021 22:06:47

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 19 APR 2021

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

Comments

If Contact Not Made, please provide Comments

US3172467

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 22 Apr 2021 16:45:20

Generated On: 11 Aug 2021 22:06:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172467

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:06:47

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3172467

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:47

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

US3172467

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:06:47

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.

US3172467

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:06:47

Was the sample collected?

Yes ☐

No ☐

Collection date (*dd MMM yyyy*)

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

Collection date and time (derived)

US3172467

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:06:47

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3172467

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:06:47

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"/>

US3172467

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:06:47

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3172467

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

Form: Visit Date

Generated On: 11 Aug 2021 22:06:47

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3172467

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

Form: Unblinding

Generated On: 11 Aug 2021 22:06:47

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

US3172467

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:06:47

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

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

US3172467

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:06:47

Was the sample collected?

Yes ☐

No ☐

Collection date (*dd MMM yyyy*)

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

Collection Date and Time (derived)

US3172467

Folder: **Unscheduled 02 Dec 2020**

Form: **Unscheduled Visit Assessment**

Data signed: (b) (4) 17 Feb 2021 13:52:13

Generated On: 11 Aug 2021 22:06:47

Visit Date	02 DEC 2020
------------	-------------

Please check all assessments that apply for this visit

Physical Exam	True
---------------	------

Vital Signs	True
-------------	------

Immunogenicity Assessment	False
---------------------------	-------

Pregnancy Test	False
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US3172467

Folder: Unscheduled 02 Dec 2020

Form: Vital Signs

Data signed: (b) (4) 17 Feb 2021 13:52:13

Generated On: 11 Aug 2021 22:06:47

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	02 DEC 2020
Time of assessment (00:00-23:59)	09:30 (24 HR)
Vital Signs Date and Time (derived)	02 DEC 2020 09:30
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3172467

Folder: Unscheduled 02 Dec 2020

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 13:52:13

Generated On: 11 Aug 2021 22:06:47

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

02 DEC 2020

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

US3172467

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 17 Feb 2021 13:52:13

Generated On: 11 Aug 2021 22:06:47

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3172467

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 17 Feb 2021 13:52:13

Generated On: 11 Aug 2021 22:06:47

AEID	USA-US118-2020-MRNA-1273-P30 1000008
Adverse event	COVID 19 SYMPTOMATIC
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	29 OCT 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)	7 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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US3172467

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 17 Feb 2021 13:52:13

Generated On: 11 Aug 2021 22:06:47

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input 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 Withdrawn <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3172467

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 17 Feb 2021 13:52:13

Generated On: 11 Aug 2021 22:06:47

AEID

Adverse event

FOLLICULITIS NECK HAIRLINE

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

16 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

02 DEC 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 17 Feb 2021 13:52:13

Generated On: 11 Aug 2021 22:06:47

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

US3172467

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 17 Feb 2021 13:52:13

Generated On: 11 Aug 2021 22:06:47

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

Yes ☒

No ☐

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

US3172467

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 17 Feb 2021 13:52:13

Generated On: 11 Aug 2021 22:06:47

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication COVID SYMPTOMS - FEVER

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 17 Feb 2021 13:52:13

Generated On: 11 Aug 2021 22:06:47

	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)		29 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		05 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3172467

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 17 Feb 2021 13:52:13

Generated On: 11 Aug 2021 22:06:47

Name of Medication AZITHROMYCIN

Prophylaxis Yes ☐
No ☒

Indication COVID 19

Dose per administration 250

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 17 Feb 2021 13:52:13

Generated On: 11 Aug 2021 22:06:47

	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)	30 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		05 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3172467

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 17 Feb 2021 13:52:13

Generated On: 11 Aug 2021 22:06:47

Name of Medication CEPHALEXIN

Prophylaxis Yes ☐
No ☒

Indication NECK HAIRLINE FOLLICULITIS

Dose per administration 500

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) 17 Feb 2021 13:52:13

Generated On: 11 Aug 2021 22:06:47

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	19 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		02 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
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="checkbox"/>

US3172467

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 17 Feb 2021 13:52:13

Generated On: 11 Aug 2021 22:06:47

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3172467

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 17 Feb 2021 13:52:13

Generated On: 11 Aug 2021 22:06:47

Date of dosing discontinuation (dd MMM yyyy) 26 NOV 2020

Primary reason for dosing discontinuation

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

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

US3172467

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:06:47

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 ☐

US3172467

Folder: SAE USA-US118-2020-MRNA-1273-P301000008

Form: Safety Report Form

Data signed: (b) (4) 17 Feb 2021 13:52:13

Generated On: 11 Aug 2021 22:06:47

SAEID	USA-US118-2020-MRNA-1273-P301000008
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3172467

Folder: SAE USA-US118-2020-MRNA-1273-P301000008

Form: Safety Report Form (1)

Data signed: (b) (4) 17 Feb 2021 13:52:13

Generated On: 11 Aug 2021 22:06:47

SAEID	USA-US118-2020-MRNA-1273-P301000008
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	06/NOV/2020 15:40
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

US3172467

Folder: SAE USA-US118-2020-MRNA-1273-P301000008

Form: Safety Report Form (2)

Data signed: (b) (4) 17 Feb 2021 13:52:13

Generated On: 11 Aug 2021 22:06:47

SAEID	USA-US118-2020-MRNA-1273-P301000008
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	16/NOV/2020 16:17
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

US3172467

Folder: SAE USA-US118-2020-MRNA-1273-P301000008

Form: Safety Report Form (3)

Data signed: (b) (4) 17 Feb 2021 13:52:13

Generated On: 11 Aug 2021 22:06:47

SAEID	USA-US118-2020-MRNA-1273-P301000008
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	30/NOV/2020 17:24
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

US3172467

Folder: SAE USA-US118-2020-MRNA-1273-P301000008

Form: Safety Report Form (4)

Data signed: (b) (4) 17 Feb 2021 13:52:13

Generated On: 11 Aug 2021 22:06:47

SAEID	USA-US118-2020-MRNA-1273-P301000008
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	08/DEC/2020 10:05
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

US3172467 (Prod: Suncoast Research Group LLC - ERN-PPDS)

US3172467

Form: Participant Creation

Generated On: 11 Aug 2021 22:06:47

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'US3172467'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	21 Oct 2020 18:13:36

US3172467

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:06:47

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:35:16

US3172467

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '21 OCT 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	21 Oct 2020 18:13:37

US3172467

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'Clinic (Clinic)'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:35:16

US3172467

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:06:47

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User entered 'SCRN'	System	21 Oct 2020 21:35:16

US3172467

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:06:47

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Year of Birth(1965) recorded on this form, however same is missing in PPD Central lab. Please reconcile the data and update as appropriate. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 12:56:29
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Year of Birth(1965) recorded on this form, however same is missing in PPD Central lab. Please reconcile the data and update as appropriate. Else clarify, thank you.' answered with 'Confirmed with lab requisition data not missing on the requisition.' (Site from DM).	Mariete Rendon (b) (4) (b) (4)	02 Nov 2020 17:20:30
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Year of Birth(1965) recorded on this form, however same is missing in PPD Central lab. Please reconcile the data and update as appropriate. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 08:15:33
User entered (b) (6) 1965'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	21 Oct 2020 18:13:38

US3172467

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:06:47

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '55'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:35:57

US3172467

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:06:47

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User entered 'YEARS'	System	21 Oct 2020 21:35:57

US3172467

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:06:47

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User entered '55'	System	21 Oct 2020 20:19:17

US3172467

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:06:47

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sex (Male) recorded on this form, however same is missing in PPD Central lab. Please reconcile the data and update as appropriate. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 10:39:42
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sex (Male) recorded on this form, however same is missing in PPD Central lab. Please reconcile the data and update as appropriate. Else clarify, thank you.' answered with 'Confirmed with lab requisition data not missing on the requisition.' (Site from DM).	Mariete Rendon (b) (4) (b) (4)	02 Nov 2020 17:20:34
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sex (Male) recorded on this form, however same is missing in PPD Central lab. Please reconcile the data and update as appropriate. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 08:15:41
User entered 'Male (M)'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:35:57

US3172467

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:06:47

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:35:57

US3172467

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:06:47

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'I'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:35:57

US3172467

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:06:47

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '0'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:35:57

US3172467

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:06:47

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '0'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:35:57

US3172467

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:06:47

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '0'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:35:57

US3172467

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:06:47

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '0'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:35:57

US3172467

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:06:47

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '0'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:35:57

US3172467

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:06:47

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:35:57

US3172467

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:06:47

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '0'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:35:57

US3172467

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:06:47

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '0'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:35:57

US3172467

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:06:47

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '21 Oct 2020'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 20:19:17

US3172467

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User entered 'Oct 2020'	System	21 Oct 2020 20:19:17

US3172467

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User entered '2020'	System	21 Oct 2020 20:19:17

US3172467

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:06:47

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'Amendment 2 (2)'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 20:19:17

US3172467

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 20:19:17

US3172467

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:06:47

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 20:19:17

US3172467

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:06:47

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 20:19:17

US3172467

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:06:47

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 20:19:17

US3172467

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:06:47

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	21 Oct 2020 18:13:37

US3172467

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:06:47

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User entered 'I'	System	21 Oct 2020 20:19:21

US3172467

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 20:19:21

US3172467

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:06:47

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:36:33

US3172467

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:06:47

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 04:34:00
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' answered with 'subject is not on treatment.' (Site from DM).	Jessie Downs (b) (4) (b) (4)	11 Jan 2021 19:35:52
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 02:34:07
User coded data point as SOC: Eye disorders, HLGT: Glaucoma and ocular hypertension, HLT: Glaucomas (excl congenital), PT: Glaucoma, LLT: Glaucoma - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 21:39:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 21:39:38
Data point term sent to Coder	System	21 Oct 2020 21:37:42
User entered 'LEFT EYE GLAUCOMA'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:36:52

US3172467

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'UN UNK 1998'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:36:52

US3172467

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:06:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '0'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:36:52

US3172467

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:06:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:36:52

US3172467

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:36:52

US3172467

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:06:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '0'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:36:52

US3172467

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:06:47

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User entered 'Jan 1998'	System	21 Oct 2020 21:36:52

US3172467

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User entered '1998'	System	21 Oct 2020 21:36:52

US3172467

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User entered empty.	System	21 Oct 2020 21:36:52

US3172467

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User entered empty.	System	21 Oct 2020 21:36:52

US3172467

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:06:47

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Presbyopia, LLT: Presbyopia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 21:39:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 21:39:38
Data point term sent to Coder	System	21 Oct 2020 21:37:42
User entered 'PRESBYOPIA'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:37:07

US3172467

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'UN UNK 2010'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:37:07

US3172467

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:06:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '0'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:37:07

US3172467

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:06:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:37:07

US3172467

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:37:07

US3172467

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:06:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '0'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:37:07

US3172467

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User entered 'Jan 2010'	System	21 Oct 2020 21:37:07

US3172467

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User entered '2010'	System	21 Oct 2020 21:37:07

US3172467

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User entered empty.	System	21 Oct 2020 21:37:07

US3172467

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User entered empty.	System	21 Oct 2020 21:37:07

US3172467

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:06:47

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Upper respiratory tract disorders (excl infections), HLT: Nasal disorders NEC, PT: Epistaxis, LLT: Nose bleeds - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 05:12:31
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 05:12:31
Data point term sent to Coder	System	21 Oct 2020 21:38:43
User entered 'OCCASIONAL NOSE BLEEDS'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:38:01

US3172467

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'UN UNK 2015'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:38:01

US3172467

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:06:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '0'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:38:01

US3172467

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:06:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:38:01

US3172467

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:38:01

US3172467

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:06:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '0'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:38:01

US3172467

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User entered 'Jan 2015'	System	21 Oct 2020 21:38:01

US3172467

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:06:47

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User entered '2015'	System	21 Oct 2020 21:38:01

US3172467

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User entered empty.	System	21 Oct 2020 21:38:01

US3172467

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User entered empty.	System	21 Oct 2020 21:38:01

US3172467

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:06:47

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Hand fracture, LLT: Hand fracture - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 12:18:26
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 12:18:26
Data point term sent to Coder	System	21 Oct 2020 21:39:45
User entered 'RIGHT SCAPHOIDE FRACTURE (RIGHT HAND)'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:38:52

US3172467

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'UN UNK 2011'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:38:52

US3172467

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:06:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '0'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:38:52

US3172467

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:06:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:38:52

US3172467

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'UN UNK 2011'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:38:52

US3172467

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:06:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '0'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:38:52

US3172467

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User entered 'Jan 2011'	System	21 Oct 2020 21:38:52

US3172467

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User entered '2011'	System	21 Oct 2020 21:38:52

US3172467

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User entered 'Jan 2011'	System	21 Oct 2020 21:38:52

US3172467

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User entered '2011'	System	21 Oct 2020 21:38:52

US3172467

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:36:20

US3172467

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '21 Oct 2020'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:36:20

US3172467

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '14:15'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:36:20

US3172467

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User entered '21 Oct 2020 14:15'	System	21 Oct 2020 21:36:20

US3172467

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:47

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '176.0' cm	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:36:20
DataPoint set to visible.	System	21 Oct 2020 20:19:21

US3172467

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '86.5' kg	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:36:20
DataPoint set to visible.	System	21 Oct 2020 20:19:21

US3172467

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:47

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User entered '27.92485'	System	21 Oct 2020 21:36:20
DataPoint set to visible.	System	21 Oct 2020 20:19:21

US3172467

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:47

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User entered 'kg/m2'	System	21 Oct 2020 21:36:20
DataPoint set to visible.	System	21 Oct 2020 20:19:21

US3172467

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:36:20

US3172467

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:36:20

US3172467

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:36:20

US3172467

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:36:20

US3172467

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User entered 'bpm'	System	21 Oct 2020 21:36:20

US3172467

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:36:20

US3172467

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User entered 'breaths/min'	System	21 Oct 2020 21:36:20

US3172467

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:47

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:36:20

US3172467

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User entered 'mmHg'	System	21 Oct 2020 21:36:20

US3172467

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:47

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:36:20

US3172467

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:47

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User entered 'mmHg'	System	21 Oct 2020 21:36:20

US3172467

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:47

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07

US3172467

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:47

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07

US3172467

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:06:47

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:36:23

US3172467

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:06:47

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:36:23

US3172467

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:35:40

US3172467

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:35:40

US3172467

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:35:40

US3172467

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:35:40

US3172467

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:35:40

US3172467

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:35:40

US3172467

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:35:40

US3172467

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:35:40

US3172467

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:35:40

US3172467

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:35:40

US3172467

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Oct 2020 15:11:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Oct 2020 15:11:01
User entered 'No (N)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 15:11:01
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 21:35:40
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:35:40

US3172467

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:06:47

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:35:40

US3172467

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:06:47

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:35:40

US3172467

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:06:47

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '0'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:35:40

US3172467

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '0'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:35:40

US3172467

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '0'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:35:40

US3172467

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'I'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:35:40

US3172467

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '0'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:35:40

US3172467

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '0'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:35:40

US3172467

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:06:47

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '0'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:35:40

US3172467

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:06:47

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:43:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:35:40

US3172467

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:06:47

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:39:01

US3172467

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:06:47

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '21 Oct 2020'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:39:01

US3172467

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'Clinic (Clinic)'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:39:01

US3172467

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:06:47

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User entered 'VISIT1'	System	21 Oct 2020 21:39:01

US3172467

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '21 OCT 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	21 Oct 2020 19:28:34

US3172467

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '117728'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	21 Oct 2020 19:28:34

US3172467

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	21 Oct 2020 19:28:34

US3172467

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:06:47

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)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:39:08

US3172467

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:06:47

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)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:39:08

US3172467

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:39:08

US3172467

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:06:47

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:39:08

US3172467

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:06:47

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:39:08

US3172467

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:39:08
DataPoint set to visible.	System	21 Oct 2020 20:19:17

US3172467

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:06:47

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:39:54

US3172467

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:06:47

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:39:54

US3172467

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:06:47

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:39:54

US3172467

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:06:47

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:39:54

US3172467

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:06:47

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User accepted default value 'Pre-Dose (PREDOSE)'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:39:54

US3172467

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:06:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:39:54

US3172467

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:06:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '21 Oct 2020'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:39:54

US3172467

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '14:15'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:39:54

US3172467

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User entered '21 Oct 2020 14:15'	System	21 Oct 2020 21:39:54

US3172467

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:06:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '37.1' C	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:39:54

US3172467

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:06:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'Oral (Oral)'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:39:54

US3172467

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:06:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:39:54

US3172467

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:06:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '77'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:39:54

US3172467

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:06:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User entered 'bpm'	System	21 Oct 2020 21:39:54

US3172467

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '16'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:39:54

US3172467

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:06:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User entered 'breaths/min'	System	21 Oct 2020 21:39:54

US3172467

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:06:47

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '106'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:39:54

US3172467

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:06:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User entered 'mmHg'	System	21 Oct 2020 21:39:54

US3172467

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:06:47

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '71'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:39:54

US3172467

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:06:47

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User entered 'mmHg'	System	21 Oct 2020 21:39:54

US3172467

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:06:47

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:39:54

US3172467

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:06:47

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:39:54

US3172467

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:06:47

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User accepted default value 'Post-Dose (POSTDOSE)'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:39:54

US3172467

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:06:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:39:54

US3172467

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:06:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '21 Oct 2020'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:39:54

US3172467

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '16:43'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:39:54

US3172467

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User entered '21 Oct 2020 16:43'	System	21 Oct 2020 21:39:54

US3172467

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:06:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '37.0' C	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:39:54

US3172467

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:06:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'Oral (Oral)'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:39:54

US3172467

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:06:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:39:54

US3172467

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:06:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '86'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:39:54

US3172467

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:06:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User entered 'bpm'	System	21 Oct 2020 21:39:54

US3172467

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '16'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:39:54

US3172467

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:06:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User entered 'breaths/min'	System	21 Oct 2020 21:39:54

US3172467

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:06:47

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '102'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:39:54

US3172467

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:06:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User entered 'mmHg'	System	21 Oct 2020 21:39:54

US3172467

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:06:47

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '64'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:39:54

US3172467

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:06:47

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User entered 'mmHg'	System	21 Oct 2020 21:39:54

US3172467

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:06:47

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:40:00

US3172467

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:06:47

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '21 Oct 2020'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:40:00

US3172467

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:06:47

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 20:19:44

US3172467

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:06:47

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 20:19:44

US3172467

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:06:47

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)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:52:15
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	21 Oct 2020 20:19:44
	(b) (4)	

US3172467

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:06:47

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User entered 'MRNA-1273 OR PLACEBO'	System	21 Oct 2020 20:19:44

US3172467

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:06:47

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:52:15
	(b) (4)	
User entered '21 Oct 2020'	Mariete Rendon (b) (4)	21 Oct 2020 20:19:44
	(b) (4)	

US3172467

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '16:13'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 20:19:44

US3172467

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User entered '21 Oct 2020 16:13'	System	21 Oct 2020 20:19:44

US3172467

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'Left Arm (LEFT ARM)'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 20:19:44

US3172467

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User entered 'ONCE'	System	21 Oct 2020 20:19:44

US3172467

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:06:47

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User entered 'INTRAMUSCULAR'	System	21 Oct 2020 20:19:44

US3172467

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:06:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:40:10

US3172467

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:06:47

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '21 Oct 2020'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:40:10

US3172467

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:06:47

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '15:39'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:40:10

US3172467

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User entered '21 Oct 2020 15:39'	System	21 Oct 2020 21:40:10

US3172467

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:06:47

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '21 Oct 2020'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:40:18

US3172467

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:06:47

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:40:18

US3172467

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:06:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:40:18

US3172467

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:06:47

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '15:42'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:40:18

US3172467

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User entered '21 Oct 2020 15:42'	System	21 Oct 2020 21:40:18

US3172467

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:06:47

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:40:18

US3172467

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:06:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:40:18

US3172467

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:06:47

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:40:18

US3172467

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User entered empty.	System	21 Oct 2020 21:40:18

US3172467

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'Yes (Y)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	02 Nov 2020 20:54:33
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:40:21

US3172467

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:06:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User entered '1'	System	02 Nov 2020 20:54:33
User entered empty.	System	21 Oct 2020 21:40:21

US3172467

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
Data entry locked.	System	21 Oct 2020 20:19:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Oct 2020 20:19:44

US3172467

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:06:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-21T16:45:14', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '52d4782c-8b37-41de-9396-755e82e4711e' User entered 'Yes (Y)'	System	21 Oct 2020 20:45:38
	System	21 Oct 2020 20:45:38

US3172467

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:06:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-21T16:45:22', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '52d4782c-8b37-41de-9396-755e82e4711e' User entered '98.5'	System	21 Oct 2020 20:45:38
	System	21 Oct 2020 20:45:38

US3172467

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-21T16:45:27', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '52d4782c-8b37-41de-9396-755e82e4711e' User entered 'No (N)'	System	21 Oct 2020 20:45:38
	System	21 Oct 2020 20:45:38

US3172467

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:06:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-21T16:45:35', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '52d4782c-8b37-41de-9396-755e82e4711e' User entered '21 Oct 2020 16:45'	System	21 Oct 2020 20:45:38
	System	21 Oct 2020 20:45:38

US3172467

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:06:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
User entered '21 Oct 2020 16:33'	System	21 Oct 2020 20:19:44

US3172467

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:06:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
User entered '21 Oct 2020 19:03'	System	21 Oct 2020 20:19:44

US3172467

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
Data entry locked.	System	21 Oct 2020 20:19:44
User entered 'Day 1, after vaccination (at home)'	System	21 Oct 2020 20:19:44

US3172467

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:06:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-21T20:00:43', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: 'd7f31c54-a61d-4376-ae20-6d68b6c398ae' User entered 'Yes (Y)'	System	22 Oct 2020 00:01:17
	System	22 Oct 2020 00:01:17

US3172467

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:06:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-21T20:00:51', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: 'd7f31c54-a61d-4376-ae20-6d68b6c398ae' User entered '98.5'	System	22 Oct 2020 00:01:17
	System	22 Oct 2020 00:01:17

US3172467

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-21T20:00:57', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: 'd7f31c54-a61d-4376-ae20-6d68b6c398ae' User entered 'No (N)'	System	22 Oct 2020 00:01:17
	System	22 Oct 2020 00:01:17

US3172467

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:06:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-21T20:01:13', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: 'd7f31c54-a61d-4376-ae20-6d68b6c398ae' User entered '21 Oct 2020 20:01'	System	22 Oct 2020 00:01:17
	System	22 Oct 2020 00:01:17

US3172467

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:06:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
User entered '21 Oct 2020 19:58'	System	21 Oct 2020 20:19:44

US3172467

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:06:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
User entered '22 Oct 2020 11:59'	System	21 Oct 2020 20:19:44

US3172467

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
Data entry locked.	System	21 Oct 2020 20:19:44
User entered 'Day 2'	System	21 Oct 2020 20:19:44

US3172467

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:06:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-22T13:08:47', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: 'bfeca879-54c6-4360-a0d9-8e116a529073' User entered 'Yes (Y)'	System	22 Oct 2020 17:09:20
	System	22 Oct 2020 17:09:20

US3172467

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:06:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-22T13:09:04', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: 'bfeca879-54c6-4360-a0d9-8e116a529073' User entered '97.0'	System	22 Oct 2020 17:09:20
	System	22 Oct 2020 17:09:20

US3172467

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-22T13:09:10', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: 'bfeca879-54c6-4360-a0d9-8e116a529073'	System	22 Oct 2020 17:09:20
User entered 'No (N)'	System	22 Oct 2020 17:09:20

US3172467

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:06:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-22T13:09:14', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: 'bfeca879-54c6-4360-a0d9-8e116a529073'	System	22 Oct 2020 17:09:20
User entered '22 Oct 2020 13:09'	System	22 Oct 2020 17:09:20

US3172467

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:06:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
User entered '22 Oct 2020 12:00'	System	21 Oct 2020 20:19:44

US3172467

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:06:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
User entered '23 Oct 2020 11:59'	System	21 Oct 2020 20:19:44

US3172467

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
Data entry locked.	System	21 Oct 2020 20:19:44
User entered 'Day 3'	System	21 Oct 2020 20:19:44

US3172467

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:06:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-23T12:00:42', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '41dfcde2-01d5-459f-ae01-2010991151cd' User entered 'Yes (Y)'	System	23 Oct 2020 16:01:42
	System	23 Oct 2020 16:01:42

US3172467

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:06:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-23T12:00:56', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '41dfcde2-01d5-459f-ae01-2010991151cd' User entered '96.0'	System	23 Oct 2020 16:01:42
	System	23 Oct 2020 16:01:42

US3172467

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-23T12:01:01', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '41dfcde2-01d5-459f-ae01-2010991151cd'	System	23 Oct 2020 16:01:42
User entered 'No (N)'	System	23 Oct 2020 16:01:42

US3172467

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:06:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-23T12:01:06', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '41dfcde2-01d5-459f-ae01-2010991151cd' User entered '23 Oct 2020 12:01'	System	23 Oct 2020 16:01:42
	System	23 Oct 2020 16:01:42

US3172467

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:06:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
User entered '23 Oct 2020 12:00'	System	21 Oct 2020 20:19:44

US3172467

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:06:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
User entered '24 Oct 2020 11:59'	System	21 Oct 2020 20:19:44

US3172467

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
Data entry locked.	System	21 Oct 2020 20:19:44
User entered 'Day 4'	System	21 Oct 2020 20:19:44

US3172467

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:06:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-24T12:50:54', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: 'a63d80cc-de8f-43cf-bad9-dcd5cbd7dc6a' User entered 'Yes (Y)'	System	24 Oct 2020 16:51:17
	System	24 Oct 2020 16:51:17

US3172467

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:06:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-24T12:51:07', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: 'a63d80cc-de8f-43cf-bad9-dcd5cbd7dc6a' User entered '96.0'	System	24 Oct 2020 16:51:17
	System	24 Oct 2020 16:51:17

US3172467

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-24T12:51:11', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: 'a63d80cc-de8f-43cf-bad9-dcd5cbd7dc6a'	System	24 Oct 2020 16:51:17
User entered 'No (N)'	System	24 Oct 2020 16:51:17

US3172467

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:06:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-24T12:51:14', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: 'a63d80cc-de8f-43cf-bad9-dcd5cbd7dc6a' User entered '24 Oct 2020 12:51'	System	24 Oct 2020 16:51:17
	System	24 Oct 2020 16:51:17

US3172467

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:06:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
User entered '24 Oct 2020 12:00'	System	21 Oct 2020 20:19:44

US3172467

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:06:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
User entered '25 Oct 2020 11:59'	System	21 Oct 2020 20:19:44

US3172467

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
Data entry locked.	System	21 Oct 2020 20:19:44
User entered 'Day 5'	System	21 Oct 2020 20:19:44

US3172467

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:06:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-25T16:24:38', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '4a874a4b-f712-428f-82e7-53acbb5edf04'	System	25 Oct 2020 20:24:55
User entered 'Yes (Y)'	System	25 Oct 2020 20:24:55

US3172467

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:06:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-25T16:24:45', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '4a874a4b-f712-428f-82e7-53acbb5edf04' User entered '98.0'	System	25 Oct 2020 20:24:55
	System	25 Oct 2020 20:24:55

US3172467

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-25T16:24:49', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '4a874a4b-f712-428f-82e7-53acbb5edf04'	System	25 Oct 2020 20:24:55
User entered 'No (N)'	System	25 Oct 2020 20:24:55

US3172467

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:06:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-25T16:24:52', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '4a874a4b-f712-428f-82e7-53acbb5edf04' User entered '25 Oct 2020 16:24'	System	25 Oct 2020 20:24:55
	System	25 Oct 2020 20:24:55

US3172467

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:06:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
User entered '25 Oct 2020 12:00'	System	21 Oct 2020 20:19:44

US3172467

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:06:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
User entered '26 Oct 2020 11:59'	System	21 Oct 2020 20:19:44

US3172467

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
Data entry locked.	System	21 Oct 2020 20:19:44
User entered 'Day 6'	System	21 Oct 2020 20:19:44

US3172467

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:06:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-26T12:00:40', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '1d438524-57ef-45a6-9b07-6ebb957a7761' User entered 'Yes (Y)'	System	26 Oct 2020 16:02:48
	System	26 Oct 2020 16:02:48

US3172467

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:06:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-26T12:00:51', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '1d438524-57ef-45a6-9b07-6ebb957a7761' User entered '96.5'	System	26 Oct 2020 16:02:48
	System	26 Oct 2020 16:02:48

US3172467

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-26T12:00:56', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '1d438524-57ef-45a6-9b07-6ebb957a7761'	System	26 Oct 2020 16:02:48
User entered 'No (N)'	System	26 Oct 2020 16:02:48

US3172467

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:06:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-26T12:00:59', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '1d438524-57ef-45a6-9b07-6ebb957a7761' User entered '26 Oct 2020 12:00'	System	26 Oct 2020 16:02:48
	System	26 Oct 2020 16:02:48

US3172467

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:06:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
User entered '26 Oct 2020 12:00'	System	21 Oct 2020 20:19:44

US3172467

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:06:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
User entered '27 Oct 2020 11:59'	System	21 Oct 2020 20:19:44

US3172467

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
Data entry locked.	System	21 Oct 2020 20:19:44
User entered 'Day 7'	System	21 Oct 2020 20:19:44

US3172467

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:06:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-27T13:42:03', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: 'cf394b65-41bf-42ba-951c-2d97b4c4b0be' User entered 'Yes (Y)'	System	27 Oct 2020 17:42:56
	System	27 Oct 2020 17:42:56

US3172467

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:06:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-27T13:42:14', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: 'cf394b65-41bf-42ba-951c-2d97b4c4b0be' User entered '98.0'	System	27 Oct 2020 17:42:56
	System	27 Oct 2020 17:42:56

US3172467

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-27T13:42:21', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: 'cf394b65-41bf-42ba-951c-2d97b4c4b0be'	System	27 Oct 2020 17:42:56
User entered 'No (N)'	System	27 Oct 2020 17:42:56

US3172467

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:06:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-27T13:42:25', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: 'cf394b65-41bf-42ba-951c-2d97b4c4b0be' User entered '27 Oct 2020 13:42'	System	27 Oct 2020 17:42:56
	System	27 Oct 2020 17:42:56

US3172467

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:06:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
User entered '27 Oct 2020 12:00'	System	21 Oct 2020 20:19:44

US3172467

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:06:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
User entered '28 Oct 2020 11:59'	System	21 Oct 2020 20:19:44

US3172467

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
Data entry locked.	System	21 Oct 2020 20:19:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Oct 2020 20:19:44

US3172467

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:06:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-21T16:46:45', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: 'c3cb128c-99e2-4ac3-a16a-34e6f7779393'	System	21 Oct 2020 20:46:55
User entered 'None (1)'	System	21 Oct 2020 20:46:55

US3172467

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:06:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-21T16:46:18', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: 'c3cb128c-99e2-4ac3-a16a-34e6f7779393'	System	21 Oct 2020 20:46:55
User entered 'No (N)'	System	21 Oct 2020 20:46:55

US3172467

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-21T16:46:22', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: 'c3cb128c-99e2-4ac3-a16a-34e6f7779393' User entered 'No (N)'	System	21 Oct 2020 20:46:55
	System	21 Oct 2020 20:46:55

US3172467

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:06:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-21T16:46:28', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: 'c3cb128c-99e2-4ac3-a16a-34e6f7779393'	System	21 Oct 2020 20:46:55
User entered 'None (1)'	System	21 Oct 2020 20:46:55

US3172467

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:06:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-21T16:46:52', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: 'c3cb128c-99e2-4ac3-a16a-34e6f7779393' User entered '21 Oct 2020 16:46'	System	21 Oct 2020 20:46:55
	System	21 Oct 2020 20:46:55

US3172467

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:06:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
User entered '21 Oct 2020 16:33'	System	21 Oct 2020 20:19:44

US3172467

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:06:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
User entered '21 Oct 2020 19:03'	System	21 Oct 2020 20:19:44

US3172467

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
Data entry locked.	System	21 Oct 2020 20:19:44
User entered 'Day 1, after vaccination (at home)'	System	21 Oct 2020 20:19:44

US3172467

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:06:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-21T20:01:22', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: 'd60a752f-1790-438b-8619-a27d530c9e57'	System	22 Oct 2020 00:01:46
User entered 'None (1)'	System	22 Oct 2020 00:01:46

US3172467

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:06:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-21T20:01:28', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: 'd60a752f-1790-438b-8619-a27d530c9e57'	System	22 Oct 2020 00:01:46
User entered 'No (N)'	System	22 Oct 2020 00:01:46

US3172467

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-21T20:01:32', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: 'd60a752f-1790-438b-8619-a27d530c9e57'	System	22 Oct 2020 00:01:46
User entered 'No (N)'	System	22 Oct 2020 00:01:46

US3172467

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:06:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-21T20:01:39', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: 'd60a752f-1790-438b-8619-a27d530c9e57'	System	22 Oct 2020 00:01:46
User entered 'None (1)'	System	22 Oct 2020 00:01:46

US3172467

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:06:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-21T20:01:44', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: 'd60a752f-1790-438b-8619-a27d530c9e57'	System	22 Oct 2020 00:01:46
User entered '21 Oct 2020 20:01'	System	22 Oct 2020 00:01:46

US3172467

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:06:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
User entered '21 Oct 2020 19:58'	System	21 Oct 2020 20:19:44

US3172467

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:06:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
User entered '22 Oct 2020 11:59'	System	21 Oct 2020 20:19:44

US3172467

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
Data entry locked.	System	21 Oct 2020 20:19:44
User entered 'Day 2'	System	21 Oct 2020 20:19:44

US3172467

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:06:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-22T13:09:21', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '97abfe71-e71b-4ca0-818e-1ec35b3d4805'	System	22 Oct 2020 17:09:45
User entered 'None (1)'	System	22 Oct 2020 17:09:45

US3172467

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:06:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-22T13:09:26', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '97abfe71-e71b-4ca0-818e-1ec35b3d4805'	System	22 Oct 2020 17:09:45
User entered 'No (N)'	System	22 Oct 2020 17:09:45

US3172467

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-22T13:09:30', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '97abfe71-e71b-4ca0-818e-1ec35b3d4805'	System	22 Oct 2020 17:09:45
User entered 'No (N)'	System	22 Oct 2020 17:09:45

US3172467

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:06:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-22T13:09:34', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '97abfe71-e71b-4ca0-818e-1ec35b3d4805'	System	22 Oct 2020 17:09:45
User entered 'None (1)'	System	22 Oct 2020 17:09:45

US3172467

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:06:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-22T13:09:39', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '97abfe71-e71b-4ca0-818e-1ec35b3d4805' User entered '22 Oct 2020 13:09'	System	22 Oct 2020 17:09:45
	System	22 Oct 2020 17:09:45

US3172467

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:06:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
User entered '22 Oct 2020 12:00'	System	21 Oct 2020 20:19:44

US3172467

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:06:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
User entered '23 Oct 2020 11:59'	System	21 Oct 2020 20:19:44

US3172467

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
Data entry locked.	System	21 Oct 2020 20:19:44
User entered 'Day 3'	System	21 Oct 2020 20:19:44

US3172467

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:06:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-23T12:01:13', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: 'd5748bed-570b-4a3f-8dd3-5633757b79ec'	System	23 Oct 2020 16:02:26
User entered 'None (1)'	System	23 Oct 2020 16:02:26

US3172467

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:06:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-23T12:01:17', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: 'd5748bed-570b-4a3f-8dd3-5633757b79ec' User entered 'No (N)'	System	23 Oct 2020 16:02:26
	System	23 Oct 2020 16:02:26

US3172467

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-23T12:01:21', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: 'd5748bed-570b-4a3f-8dd3-5633757b79ec' User entered 'No (N)'	System	23 Oct 2020 16:02:26
	System	23 Oct 2020 16:02:26

US3172467

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:06:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-23T12:01:31', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: 'd5748bed-570b-4a3f-8dd3-5633757b79ec'	System	23 Oct 2020 16:02:26
User entered 'None (1)'	System	23 Oct 2020 16:02:26

US3172467

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:06:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-23T12:01:35', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: 'd5748bed-570b-4a3f-8dd3-5633757b79ec' User entered '23 Oct 2020 12:01'	System	23 Oct 2020 16:02:26
	System	23 Oct 2020 16:02:26

US3172467

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:06:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
User entered '23 Oct 2020 12:00'	System	21 Oct 2020 20:19:44

US3172467

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:06:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
User entered '24 Oct 2020 11:59'	System	21 Oct 2020 20:19:44

US3172467

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
Data entry locked.	System	21 Oct 2020 20:19:44
User entered 'Day 4'	System	21 Oct 2020 20:19:44

US3172467

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:06:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-24T12:51:21', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '083fd574-a0e0-4507-950f-c9db62254b9e'	System	24 Oct 2020 16:51:40
User entered 'None (1)'	System	24 Oct 2020 16:51:40

US3172467

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:06:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-24T12:51:26', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '083fd574-a0e0-4507-950f-c9db62254b9e'	System	24 Oct 2020 16:51:40
User entered 'No (N)'	System	24 Oct 2020 16:51:40

US3172467

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-24T12:51:30', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '083fd574-a0e0-4507-950f-c9db62254b9e'	System	24 Oct 2020 16:51:40
User entered 'No (N)'	System	24 Oct 2020 16:51:40

US3172467

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:06:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-24T12:51:34', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '083fd574-a0e0-4507-950f-c9db62254b9e'	System	24 Oct 2020 16:51:40
User entered 'None (1)'	System	24 Oct 2020 16:51:40

US3172467

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:06:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-24T12:51:37', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '083fd574-a0e0-4507-950f-c9db62254b9e'	System	24 Oct 2020 16:51:40
User entered '24 Oct 2020 12:51'	System	24 Oct 2020 16:51:40

US3172467

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:06:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
User entered '24 Oct 2020 12:00'	System	21 Oct 2020 20:19:44

US3172467

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:06:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
User entered '25 Oct 2020 11:59'	System	21 Oct 2020 20:19:44

US3172467

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
Data entry locked.	System	21 Oct 2020 20:19:44
User entered 'Day 5'	System	21 Oct 2020 20:19:44

US3172467

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:06:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-25T16:24:58', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '896df338-8e00-437a-b563-cb347b192d59'	System	25 Oct 2020 20:25:16
User entered 'None (1)'	System	25 Oct 2020 20:25:16

US3172467

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:06:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-25T16:25:01', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '896df338-8e00-437a-b563-cb347b192d59'	System	25 Oct 2020 20:25:16
User entered 'No (N)'	System	25 Oct 2020 20:25:16

US3172467

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-25T16:25:07', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '896df338-8e00-437a-b563-cb347b192d59'	System	25 Oct 2020 20:25:16
User entered 'No (N)'	System	25 Oct 2020 20:25:16

US3172467

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:06:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-25T16:25:11', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '896df338-8e00-437a-b563-cb347b192d59'	System	25 Oct 2020 20:25:16
User entered 'None (1)'	System	25 Oct 2020 20:25:16

US3172467

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:06:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-25T16:25:14', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '896df338-8e00-437a-b563-cb347b192d59' User entered '25 Oct 2020 16:25'	System	25 Oct 2020 20:25:16
	System	25 Oct 2020 20:25:16

US3172467

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:06:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
User entered '25 Oct 2020 12:00'	System	21 Oct 2020 20:19:44

US3172467

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:06:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
User entered '26 Oct 2020 11:59'	System	21 Oct 2020 20:19:44

US3172467

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
Data entry locked.	System	21 Oct 2020 20:19:44
User entered 'Day 6'	System	21 Oct 2020 20:19:44

US3172467

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:06:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-26T12:01:05', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: 'b78f883f-94ca-4586-8df6-e9106674191b'	System	26 Oct 2020 16:03:09
User entered 'None (1)'	System	26 Oct 2020 16:03:09

US3172467

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:06:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-26T12:01:09', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: 'b78f883f-94ca-4586-8df6-e9106674191b'	System	26 Oct 2020 16:03:09
User entered 'No (N)'	System	26 Oct 2020 16:03:09

US3172467

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-26T12:01:11', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: 'b78f883f-94ca-4586-8df6-e9106674191b' User entered 'No (N)'	System	26 Oct 2020 16:03:09
	System	26 Oct 2020 16:03:09

US3172467

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:06:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-26T12:01:14', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: 'b78f883f-94ca-4586-8df6-e9106674191b'	System	26 Oct 2020 16:03:09
User entered 'None (1)'	System	26 Oct 2020 16:03:09

US3172467

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:06:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-26T12:01:17', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: 'b78f883f-94ca-4586-8df6-e9106674191b' User entered '26 Oct 2020 12:01'	System	26 Oct 2020 16:03:09
	System	26 Oct 2020 16:03:09

US3172467

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:06:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
User entered '26 Oct 2020 12:00'	System	21 Oct 2020 20:19:44

US3172467

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:06:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
User entered '27 Oct 2020 11:59'	System	21 Oct 2020 20:19:44

US3172467

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
Data entry locked.	System	21 Oct 2020 20:19:44
User entered 'Day 7'	System	21 Oct 2020 20:19:44

US3172467

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:06:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-27T13:42:29', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: 'dd8bd47f-05a0-4af2-bb2c-58d88df8d6d9'	System	27 Oct 2020 17:43:07
User entered 'None (1)'	System	27 Oct 2020 17:43:07

US3172467

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:06:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-27T13:42:34', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: 'dd8bd47f-05a0-4af2-bb2c-58d88df8d6d9' User entered 'No (N)'	System	27 Oct 2020 17:43:07
	System	27 Oct 2020 17:43:07

US3172467

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-27T13:42:37', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: 'dd8bd47f-05a0-4af2-bb2c-58d88df8d6d9' User entered 'No (N)'	System	27 Oct 2020 17:43:07
	System	27 Oct 2020 17:43:07

US3172467

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:06:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-27T13:42:43', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: 'dd8bd47f-05a0-4af2-bb2c-58d88df8d6d9'	System	27 Oct 2020 17:43:07
User entered 'None (1)'	System	27 Oct 2020 17:43:07

US3172467

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:06:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-27T13:42:46', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: 'dd8bd47f-05a0-4af2-bb2c-58d88df8d6d9' User entered '27 Oct 2020 13:42'	System	27 Oct 2020 17:43:07
	System	27 Oct 2020 17:43:07

US3172467

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:06:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
User entered '27 Oct 2020 12:00'	System	21 Oct 2020 20:19:44

US3172467

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:06:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
User entered '28 Oct 2020 11:59'	System	21 Oct 2020 20:19:44

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
Data entry locked.	System	21 Oct 2020 20:19:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Oct 2020 20:19:44

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:06:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-21T16:46:58', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '0f1a4ed5-f5f2-4b02-8926-4b92ef62c8d2'	System	21 Oct 2020 20:47:38
User entered 'None (0)'	System	21 Oct 2020 20:47:38

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:06:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-21T16:47:03', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '0f1a4ed5-f5f2-4b02-8926-4b92ef62c8d2'	System	21 Oct 2020 20:47:38
User entered 'None (0)'	System	21 Oct 2020 20:47:38

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:06:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-21T16:47:07', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '0f1a4ed5-f5f2-4b02-8926-4b92ef62c8d2'	System	21 Oct 2020 20:47:38
User entered 'None (0)'	System	21 Oct 2020 20:47:38

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:06:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-21T16:47:10', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '0f1a4ed5-f5f2-4b02-8926-4b92ef62c8d2' User entered 'None (0)'	System	21 Oct 2020 20:47:38
	System	21 Oct 2020 20:47:38

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:06:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-21T16:47:13', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '0f1a4ed5-f5f2-4b02-8926-4b92ef62c8d2' User entered 'None (0)'	System	21 Oct 2020 20:47:38
	System	21 Oct 2020 20:47:38

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:06:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-21T16:47:16', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '0f1a4ed5-f5f2-4b02-8926-4b92ef62c8d2' User entered 'None (0)'	System	21 Oct 2020 20:47:38
	System	21 Oct 2020 20:47:38

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-21T16:47:26', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '0f1a4ed5-f5f2-4b02-8926-4b92ef62c8d2'	System	21 Oct 2020 20:47:38
User entered 'No (N)'	System	21 Oct 2020 20:47:38

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:06:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-21T16:47:34', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '0f1a4ed5-f5f2-4b02-8926-4b92ef62c8d2'	System	21 Oct 2020 20:47:38
User entered '21 Oct 2020 16:47'	System	21 Oct 2020 20:47:38

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:06:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
User entered '21 Oct 2020 16:33'	System	21 Oct 2020 20:19:44

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:06:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
User entered '21 Oct 2020 19:03'	System	21 Oct 2020 20:19:44

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
Data entry locked.	System	21 Oct 2020 20:19:44
User entered 'Day 1, after vaccination (at home)'	System	21 Oct 2020 20:19:44

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:06:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-21T20:01:51', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '65bb3797-b2dc-4725-af0a-b11b71ea7776' User entered 'None (0)'	System	22 Oct 2020 00:03:01
	System	22 Oct 2020 00:03:01

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:06:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-21T20:01:54', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '65bb3797-b2dc-4725-af0a-b11b71ea7776' User entered 'None (0)'	System	22 Oct 2020 00:03:01
	System	22 Oct 2020 00:03:01

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:06:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-21T20:01:57', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '65bb3797-b2dc-4725-af0a-b11b71ea7776' User entered 'None (0)'	System	22 Oct 2020 00:03:01
	System	22 Oct 2020 00:03:01

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:06:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-21T20:02:01', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '65bb3797-b2dc-4725-af0a-b11b71ea7776' User entered 'None (0)'	System	22 Oct 2020 00:03:01
	System	22 Oct 2020 00:03:01

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:06:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-21T20:02:04', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '65bb3797-b2dc-4725-af0a-b11b71ea7776' User entered 'None (0)'	System	22 Oct 2020 00:03:01
	System	22 Oct 2020 00:03:01

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:06:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-21T20:02:09', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '65bb3797-b2dc-4725-af0a-b11b71ea7776' User entered 'None (0)'	System	22 Oct 2020 00:03:01
	System	22 Oct 2020 00:03:01

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-21T20:02:49', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '65bb3797-b2dc-4725-af0a-b11b71ea7776' User entered 'No (N)'	System	22 Oct 2020 00:03:01
	System	22 Oct 2020 00:03:01

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:06:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-21T20:02:58', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '65bb3797-b2dc-4725-af0a-b11b71ea7776' User entered '21 Oct 2020 20:02'	System	22 Oct 2020 00:03:01
	System	22 Oct 2020 00:03:01

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:06:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
User entered '21 Oct 2020 19:58'	System	21 Oct 2020 20:19:44

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:06:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
User entered '22 Oct 2020 11:59'	System	21 Oct 2020 20:19:44

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
Data entry locked.	System	21 Oct 2020 20:19:44
User entered 'Day 2'	System	21 Oct 2020 20:19:44

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:06:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-22T13:09:45', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '79e70ecd-89a4-477a-9a2b-158863a6ce05' User entered 'None (0)'	System	22 Oct 2020 17:10:22
	System	22 Oct 2020 17:10:22

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:06:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-22T13:09:48', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '79e70ecd-89a4-477a-9a2b-158863a6ce05' User entered 'None (0)'	System	22 Oct 2020 17:10:22
	System	22 Oct 2020 17:10:22

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:06:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-22T13:09:52', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '79e70ecd-89a4-477a-9a2b-158863a6ce05' User entered 'None (0)'	System	22 Oct 2020 17:10:22
	System	22 Oct 2020 17:10:22

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:06:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-22T13:09:57', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '79e70ecd-89a4-477a-9a2b-158863a6ce05' User entered 'None (0)'	System	22 Oct 2020 17:10:22
	System	22 Oct 2020 17:10:22

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:06:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-22T13:10:01', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '79e70ecd-89a4-477a-9a2b-158863a6ce05' User entered 'None (0)'	System	22 Oct 2020 17:10:22
	System	22 Oct 2020 17:10:22

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:06:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-22T13:10:03', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '79e70ecd-89a4-477a-9a2b-158863a6ce05' User entered 'None (0)'	System	22 Oct 2020 17:10:22
	System	22 Oct 2020 17:10:22

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-22T13:10:10', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '79e70ecd-89a4-477a-9a2b-158863a6ce05' User entered 'No (N)'	System	22 Oct 2020 17:10:22
	System	22 Oct 2020 17:10:22

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:06:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-22T13:10:13', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '79e70ecd-89a4-477a-9a2b-158863a6ce05' User entered '22 Oct 2020 13:10'	System	22 Oct 2020 17:10:22
	System	22 Oct 2020 17:10:22

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:06:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
User entered '22 Oct 2020 12:00'	System	21 Oct 2020 20:19:44

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:06:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
User entered '23 Oct 2020 11:59'	System	21 Oct 2020 20:19:44

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
Data entry locked.	System	21 Oct 2020 20:19:44
User entered 'Day 3'	System	21 Oct 2020 20:19:44

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:06:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-23T12:01:43', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '5ba58a7b-420c-4940-b20f-a60554150b08' User entered 'None (0)'	System	23 Oct 2020 16:03:56
	System	23 Oct 2020 16:03:56

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:06:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-23T12:01:51', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '5ba58a7b-420c-4940-b20f-a60554150b08' User entered 'None (0)'	System	23 Oct 2020 16:03:56
	System	23 Oct 2020 16:03:56

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:06:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-23T12:01:55', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '5ba58a7b-420c-4940-b20f-a60554150b08' User entered 'None (0)'	System	23 Oct 2020 16:03:56
	System	23 Oct 2020 16:03:56

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:06:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-23T12:02:00', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '5ba58a7b-420c-4940-b20f-a60554150b08' User entered 'None (0)'	System	23 Oct 2020 16:03:56
	System	23 Oct 2020 16:03:56

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:06:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-23T12:02:04', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '5ba58a7b-420c-4940-b20f-a60554150b08' User entered 'None (0)'	System	23 Oct 2020 16:03:56
	System	23 Oct 2020 16:03:56

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:06:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-23T12:02:06', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '5ba58a7b-420c-4940-b20f-a60554150b08' User entered 'None (0)'	System	23 Oct 2020 16:03:56
	System	23 Oct 2020 16:03:56

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-23T12:02:20', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '5ba58a7b-420c-4940-b20f-a60554150b08' User entered 'No (N)'	System	23 Oct 2020 16:03:56
	System	23 Oct 2020 16:03:56

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:06:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-23T12:02:24', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '5ba58a7b-420c-4940-b20f-a60554150b08' User entered '23 Oct 2020 12:02'	System	23 Oct 2020 16:03:56
	System	23 Oct 2020 16:03:56

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:06:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
User entered '23 Oct 2020 12:00'	System	21 Oct 2020 20:19:44

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:06:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
User entered '24 Oct 2020 11:59'	System	21 Oct 2020 20:19:44

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
Data entry locked.	System	21 Oct 2020 20:19:44
User entered 'Day 4'	System	21 Oct 2020 20:19:44

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:06:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-24T12:51:44', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '4fb8a0b3-c2d6-4b21-84ec-ca08bb4c9d4f' User entered 'None (0)'	System	24 Oct 2020 16:52:17
	System	24 Oct 2020 16:52:17

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:06:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-24T12:51:50', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '4fb8a0b3-c2d6-4b21-84ec-ca08bb4c9d4f' User entered 'None (0)'	System	24 Oct 2020 16:52:17
	System	24 Oct 2020 16:52:17

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:06:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-24T12:51:54', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '4fb8a0b3-c2d6-4b21-84ec-ca08bb4c9d4f' User entered 'None (0)'	System	24 Oct 2020 16:52:17
	System	24 Oct 2020 16:52:17

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:06:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-24T12:51:59', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '4fb8a0b3-c2d6-4b21-84ec-ca08bb4c9d4f' User entered 'None (0)'	System	24 Oct 2020 16:52:17
	System	24 Oct 2020 16:52:17

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:06:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-24T12:52:02', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '4fb8a0b3-c2d6-4b21-84ec-ca08bb4c9d4f' User entered 'None (0)'	System	24 Oct 2020 16:52:17
	System	24 Oct 2020 16:52:17

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:06:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-24T12:52:05', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '4fb8a0b3-c2d6-4b21-84ec-ca08bb4c9d4f' User entered 'None (0)'	System	24 Oct 2020 16:52:17
	System	24 Oct 2020 16:52:17

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-24T12:52:12', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '4fb8a0b3-c2d6-4b21-84ec-ca08bb4c9d4f' User entered 'No (N)'	System	24 Oct 2020 16:52:17
	System	24 Oct 2020 16:52:17

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:06:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-24T12:52:15', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '4fb8a0b3-c2d6-4b21-84ec-ca08bb4c9d4f' User entered '24 Oct 2020 12:52'	System	24 Oct 2020 16:52:17
	System	24 Oct 2020 16:52:17

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:06:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
User entered '24 Oct 2020 12:00'	System	21 Oct 2020 20:19:44

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:06:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
User entered '25 Oct 2020 11:59'	System	21 Oct 2020 20:19:44

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
Data entry locked.	System	21 Oct 2020 20:19:44
User entered 'Day 5'	System	21 Oct 2020 20:19:44

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:06:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-25T16:25:18', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: 'a309ea92-eaf5-4522-8b43-1ac109efa6bc' User entered 'None (0)'	System	25 Oct 2020 20:25:46
	System	25 Oct 2020 20:25:46

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:06:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-25T16:25:21', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: 'a309ea92-eaf5-4522-8b43-1ac109efa6bc' User entered 'None (0)'	System	25 Oct 2020 20:25:46
	System	25 Oct 2020 20:25:46

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:06:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-25T16:25:24', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: 'a309ea92-eaf5-4522-8b43-1ac109efa6bc' User entered 'None (0)'	System	25 Oct 2020 20:25:46
	System	25 Oct 2020 20:25:46

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:06:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-25T16:25:27', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: 'a309ea92-eaf5-4522-8b43-1ac109efa6bc' User entered 'None (0)'	System	25 Oct 2020 20:25:46
	System	25 Oct 2020 20:25:46

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:06:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-25T16:25:30', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: 'a309ea92-eaf5-4522-8b43-1ac109efa6bc' User entered 'None (0)'	System	25 Oct 2020 20:25:46
	System	25 Oct 2020 20:25:46

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:06:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-25T16:25:34', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: 'a309ea92-eaf5-4522-8b43-1ac109efa6bc' User entered 'None (0)'	System	25 Oct 2020 20:25:46
	System	25 Oct 2020 20:25:46

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-25T16:25:40', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: 'a309ea92-eaf5-4522-8b43-1ac109efa6bc' User entered 'No (N)'	System	25 Oct 2020 20:25:46
	System	25 Oct 2020 20:25:46

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:06:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-25T16:25:43', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: 'a309ea92-eaf5-4522-8b43-1ac109efa6bc' User entered '25 Oct 2020 16:25'	System	25 Oct 2020 20:25:46
	System	25 Oct 2020 20:25:46

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:06:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
User entered '25 Oct 2020 12:00'	System	21 Oct 2020 20:19:44

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:06:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
User entered '26 Oct 2020 11:59'	System	21 Oct 2020 20:19:44

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
Data entry locked.	System	21 Oct 2020 20:19:44
User entered 'Day 6'	System	21 Oct 2020 20:19:44

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:06:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-26T12:01:23', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: 'eaf9d774-6c15-44cf-8b79-481eb4ef830a' User entered 'None (0)'	System	26 Oct 2020 16:03:47
	System	26 Oct 2020 16:03:47

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:06:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-26T12:01:27', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: 'eaf9d774-6c15-44cf-8b79-481eb4ef830a' User entered 'None (0)'	System	26 Oct 2020 16:03:47
	System	26 Oct 2020 16:03:47

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:06:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-26T12:01:31', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: 'eaf9d774-6c15-44cf-8b79-481eb4ef830a' User entered 'None (0)'	System	26 Oct 2020 16:03:47
	System	26 Oct 2020 16:03:47

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:06:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-26T12:01:33', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: 'eaf9d774-6c15-44cf-8b79-481eb4ef830a' User entered 'None (0)'	System	26 Oct 2020 16:03:47
	System	26 Oct 2020 16:03:47

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:06:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-26T12:01:37', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: 'eaf9d774-6c15-44cf-8b79-481eb4ef830a' User entered 'None (0)'	System	26 Oct 2020 16:03:47
	System	26 Oct 2020 16:03:47

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:06:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-26T12:01:44', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: 'eaf9d774-6c15-44cf-8b79-481eb4ef830a' User entered 'None (0)'	System	26 Oct 2020 16:03:47
	System	26 Oct 2020 16:03:47

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-26T12:01:51', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: 'eaf9d774-6c15-44cf-8b79-481eb4ef830a' User entered 'No (N)'	System	26 Oct 2020 16:03:47
	System	26 Oct 2020 16:03:47

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:06:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-26T12:01:54', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: 'eaf9d774-6c15-44cf-8b79-481eb4ef830a' User entered '26 Oct 2020 12:01'	System	26 Oct 2020 16:03:47
	System	26 Oct 2020 16:03:47

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:06:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
User entered '26 Oct 2020 12:00'	System	21 Oct 2020 20:19:44

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:06:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
User entered '27 Oct 2020 11:59'	System	21 Oct 2020 20:19:44

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
Data entry locked.	System	21 Oct 2020 20:19:44
User entered 'Day 7'	System	21 Oct 2020 20:19:44

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:06:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-27T13:42:50', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: 'b1fd007a-54c2-4412-837b-6490019d2433'	System	27 Oct 2020 17:43:18
User entered 'None (0)'	System	27 Oct 2020 17:43:18

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:06:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-27T13:42:53', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: 'b1fd007a-54c2-4412-837b-6490019d2433'	System	27 Oct 2020 17:43:18
User entered 'None (0)'	System	27 Oct 2020 17:43:18

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:06:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-27T13:42:55', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: 'b1fd007a-54c2-4412-837b-6490019d2433'	System	27 Oct 2020 17:43:18
User entered 'None (0)'	System	27 Oct 2020 17:43:18

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:06:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-27T13:42:58', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: 'b1fd007a-54c2-4412-837b-6490019d2433' User entered 'None (0)'	System	27 Oct 2020 17:43:18
	System	27 Oct 2020 17:43:18

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:06:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-27T13:43:01', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: 'b1fd007a-54c2-4412-837b-6490019d2433'	System	27 Oct 2020 17:43:18
User entered 'None (0)'	System	27 Oct 2020 17:43:18

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:06:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-27T13:43:04', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: 'b1fd007a-54c2-4412-837b-6490019d2433'	System	27 Oct 2020 17:43:18
User entered 'None (0)'	System	27 Oct 2020 17:43:18

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-27T13:43:13', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: 'b1fd007a-54c2-4412-837b-6490019d2433'	System	27 Oct 2020 17:43:18
User entered 'No (N)'	System	27 Oct 2020 17:43:18

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:06:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-10-27T13:43:16', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: 'b1fd007a-54c2-4412-837b-6490019d2433'	System	27 Oct 2020 17:43:18
User entered '27 Oct 2020 13:43'	System	27 Oct 2020 17:43:18

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:06:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
User entered '27 Oct 2020 12:00'	System	21 Oct 2020 20:19:44

US3172467

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:06:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:03
User entered '28 Oct 2020 11:59'	System	21 Oct 2020 20:19:44

US3172467

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	02 Nov 2020 20:55:46

US3172467

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '30 Oct 2020'	Mariete Rendon (b) (4) (b) (4)	02 Nov 2020 20:55:46

US3172467

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'Contact Not Made (CONTACT NOT MADE)'	Mariete Rendon (b) (4) (b) (4)	02 Nov 2020 20:55:46

US3172467

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'unable to contact subject. Left message.'	Mariete Rendon (b) (4) (b) (4)	02 Nov 2020 20:55:46

US3172467

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	12 Nov 2020 20:49:09
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	02 Nov 2020 20:55:50

US3172467

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:06:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User entered '1'	System	12 Nov 2020 20:49:09
User entered empty.	System	02 Nov 2020 20:55:50

US3172467

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	12 Nov 2020 20:49:24

US3172467

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:52:15
	(b) (4)	
User entered '05 Nov 2020'	Jessie Downs (b) (4)	12 Nov 2020 20:49:24
	(b) (4)	

US3172467

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	12 Nov 2020 20:49:24

US3172467

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered empty.	Jessie Downs (b) (4) (b) (4)	12 Nov 2020 20:49:24

US3172467

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	12 Nov 2020 20:49:28

US3172467

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:06:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User entered 'I'	System	12 Nov 2020 20:49:28

US3172467

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	12 Nov 2020 20:49:44

US3172467

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:52:15
	(b) (4)	
User entered '12 Nov 2020'	Jessie Downs (b) (4)	12 Nov 2020 20:49:44
	(b) (4)	

US3172467

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	12 Nov 2020 20:49:44

US3172467

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered empty.	Jessie Downs (b) (4) (b) (4)	12 Nov 2020 20:49:44

US3172467

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	12 Nov 2020 20:49:48

US3172467

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:06:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User entered 'I'	System	12 Nov 2020 20:49:48

US3172467

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:06:47

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	20 Nov 2020 21:27:08

US3172467

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:06:47

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '18 Nov 2020'	Mariete Rendon (b) (4) (b) (4)	20 Nov 2020 21:27:08

US3172467

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'Clinic (Clinic)'	Mariete Rendon (b) (4) (b) (4)	20 Nov 2020 21:27:08

US3172467

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:06:47

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User entered 'VISIT2'	System	20 Nov 2020 21:27:08

US3172467

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:06:47

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User accepted default value 'Pre-Dose (PREDOSE)'	Mariete Rendon (b) (4) (b) (4)	20 Nov 2020 21:28:20

US3172467

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:06:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	20 Nov 2020 21:28:20

US3172467

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:06:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '18 Nov 2020'	Mariete Rendon (b) (4) (b) (4)	20 Nov 2020 21:28:20

US3172467

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '11:12'	Mariete Rendon (b) (4) (b) (4)	20 Nov 2020 21:28:20

US3172467

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User entered '18 Nov 2020 11:12'	System	20 Nov 2020 21:28:20

US3172467

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:06:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '36.9' C	Mariete Rendon (b) (4) (b) (4)	20 Nov 2020 21:28:20

US3172467

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:06:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'Oral (Oral)'	Mariete Rendon (b) (4) (b) (4)	20 Nov 2020 21:28:20

US3172467

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:06:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered empty.	Mariete Rendon (b) (4) (b) (4)	20 Nov 2020 21:28:20

US3172467

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:06:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '73'	Mariete Rendon (b) (4) (b) (4)	20 Nov 2020 21:28:20

US3172467

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:06:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User entered 'bpm'	System	20 Nov 2020 21:28:20

US3172467

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '15'	Mariete Rendon (b) (4) (b) (4)	20 Nov 2020 21:28:20

US3172467

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:06:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User entered 'breaths/min'	System	20 Nov 2020 21:28:20

US3172467

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:06:47

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '128'	Mariete Rendon (b) (4) (b) (4)	20 Nov 2020 21:28:20

US3172467

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:06:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User entered 'mmHg'	System	20 Nov 2020 21:28:20

US3172467

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:06:47

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '77'	Mariete Rendon (b) (4) (b) (4)	20 Nov 2020 21:28:20

US3172467

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:06:47

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User entered 'mmHg'	System	20 Nov 2020 21:28:20

US3172467

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:06:47

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User accepted default value 'Post-Dose (POSTDOSE)'	Mariete Rendon (b) (4) (b) (4)	20 Nov 2020 21:28:20

US3172467

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:06:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	20 Nov 2020 21:28:20

US3172467

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:06:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered empty.	Mariete Rendon (b) (4) (b) (4)	20 Nov 2020 21:28:20

US3172467

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered empty.	Mariete Rendon (b) (4) (b) (4)	20 Nov 2020 21:28:20

US3172467

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User entered empty.	System	20 Nov 2020 21:28:20

US3172467

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:06:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered empty.	Mariete Rendon (b) (4) (b) (4)	20 Nov 2020 21:28:20

US3172467

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:06:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered empty.	Mariete Rendon (b) (4) (b) (4)	20 Nov 2020 21:28:20

US3172467

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:06:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered empty.	Mariete Rendon (b) (4) (b) (4)	20 Nov 2020 21:28:20

US3172467

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:06:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered empty.	Mariete Rendon (b) (4) (b) (4)	20 Nov 2020 21:28:20

US3172467

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:06:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User entered empty.	System	20 Nov 2020 21:28:20

US3172467

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered empty.	Mariete Rendon (b) (4) (b) (4)	20 Nov 2020 21:28:20

US3172467

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:06:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User entered empty.	System	20 Nov 2020 21:28:20

US3172467

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:06:47

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered empty.	Mariete Rendon (b) (4) (b) (4)	20 Nov 2020 21:28:20

US3172467

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:06:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User entered empty.	System	20 Nov 2020 21:28:20

US3172467

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:06:47

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered empty.	Mariete Rendon (b) (4) (b) (4)	20 Nov 2020 21:28:20

US3172467

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:06:47

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User entered empty.	System	20 Nov 2020 21:28:20

US3172467

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:06:47

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	20 Nov 2020 21:28:27

US3172467

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:06:47

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '18 Nov 2020'	Mariete Rendon (b) (4) (b) (4)	20 Nov 2020 21:28:27

US3172467

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:06:47

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	20 Nov 2020 21:28:35

US3172467

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:06:47

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User closed query 'Per CDM: Response Noted. Please update the Dosing Discontinuation form under end of study folder accordingly else clarify. Thank you. ' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 20:21:21
Query 'Per CDM: Response Noted. Please update the Dosing Discontinuation form under end of study folder accordingly else clarify. Thank you. ' answered with 'Data updated' (Site from DM).	Mariete Rendon (b) (4) (b) (4)	30 Nov 2020 13:58:08
User opened query 'Per CDM: Response Noted. Please update the Dosing Discontinuation form under end of study folder accordingly else clarify. Thank you. ' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 03:18:31
User entered 'Confirmed COVID-19 (COVID)'	Mariete Rendon (b) (4) (b) (4)	20 Nov 2020 21:28:35

US3172467

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:06:47

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)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered empty.	Mariete Rendon (b) (4) (b) (4)	20 Nov 2020 21:28:35

US3172467

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:06:47

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User entered empty.	System	20 Nov 2020 21:28:35

US3172467

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:06:47

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered empty.	Mariete Rendon (b) (4) (b) (4)	20 Nov 2020 21:28:35

US3172467

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered empty.	Mariete Rendon (b) (4) (b) (4)	20 Nov 2020 21:28:35

US3172467

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User entered empty.	System	20 Nov 2020 21:28:35

US3172467

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered empty.	Mariete Rendon (b) (4) (b) (4)	20 Nov 2020 21:28:35

US3172467

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User entered empty.	System	20 Nov 2020 21:28:35

US3172467

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:06:47

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User entered empty.	System	20 Nov 2020 21:28:35

US3172467

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:06:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	20 Nov 2020 21:28:52

US3172467

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:06:47

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '18 Nov 2020'	Mariete Rendon (b) (4) (b) (4)	20 Nov 2020 21:28:52

US3172467

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:06:47

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '13:07'	Mariete Rendon (b) (4) (b) (4)	20 Nov 2020 21:28:52

US3172467

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User entered '18 Nov 2020 13:07'	System	20 Nov 2020 21:28:52

US3172467

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:06:47

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '18 Nov 2020'	Mariete Rendon (b) (4) (b) (4)	20 Nov 2020 21:29:01

US3172467

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:06:47

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Mariete Rendon (b) (4) (b) (4)	20 Nov 2020 21:29:01

US3172467

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:06:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	20 Nov 2020 21:29:01

US3172467

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:06:47

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '13:09'	Mariete Rendon (b) (4) (b) (4)	20 Nov 2020 21:29:01

US3172467

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User entered '18 Nov 2020 13:09'	System	20 Nov 2020 21:29:01

US3172467

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:06:47

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Mariete Rendon (b) (4) (b) (4)	20 Nov 2020 21:29:01

US3172467

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:06:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	20 Nov 2020 21:29:01

US3172467

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:06:47

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered empty.	Mariete Rendon (b) (4) (b) (4)	20 Nov 2020 21:29:01

US3172467

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User entered empty.	System	20 Nov 2020 21:29:01

US3172467

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	20 Nov 2020 21:29:05

US3172467

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:06:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User entered '1'	System	20 Nov 2020 21:29:05

US3172467

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	25 Nov 2020 21:06:58

US3172467

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:52:15
	(b) (4)	
User entered '25 Nov 2020'	Mariete Rendon (b) (4)	25 Nov 2020 21:06:58
	(b) (4)	

US3172467

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:52:15
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Mariete Rendon (b) (4)	25 Nov 2020 21:06:58
	(b) (4)	

US3172467

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered empty.	Mariete Rendon (b) (4) (b) (4)	25 Nov 2020 21:06:58

US3172467

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	25 Nov 2020 21:07:09

US3172467

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:06:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User entered 'I'	System	25 Nov 2020 21:07:09

US3172467

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	02 Dec 2020 22:19:10

US3172467

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '02 Dec 2020'	Jessie Downs (b) (4) (b) (4)	02 Dec 2020 22:19:10

US3172467

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	02 Dec 2020 22:19:10

US3172467

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered empty.	Jessie Downs (b) (4) (b) (4)	02 Dec 2020 22:19:10

US3172467

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	02 Dec 2020 22:19:16

US3172467

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:06:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User entered 'I'	System	02 Dec 2020 22:19:16

US3172467

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	10 Dec 2020 20:25:05

US3172467

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '09 Dec 2020'	Jessie Downs (b) (4) (b) (4)	10 Dec 2020 20:25:05

US3172467

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	10 Dec 2020 20:25:05

US3172467

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered empty.	Jessie Downs (b) (4) (b) (4)	10 Dec 2020 20:25:05

US3172467

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	10 Dec 2020 20:25:27

US3172467

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:06:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User entered 'I'	System	10 Dec 2020 20:25:27

US3172467

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:06:47

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	17 Dec 2020 21:26:21

US3172467

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '16 Dec 2020'	Jessie Downs (b) (4) (b) (4)	17 Dec 2020 21:26:21

US3172467

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'Clinic (Clinic)'	Jessie Downs (b) (4) (b) (4)	17 Dec 2020 21:26:21

US3172467

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:06:47

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User entered 'VISIT3'	System	17 Dec 2020 21:26:21

US3172467

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	17 Dec 2020 21:26:55

US3172467

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '16 Dec 2020'	Jessie Downs (b) (4) (b) (4)	17 Dec 2020 21:26:55

US3172467

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '12:06'	Jessie Downs (b) (4) (b) (4)	17 Dec 2020 21:26:55

US3172467

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User entered '16 Dec 2020 12:06'	System	17 Dec 2020 21:26:55

US3172467

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '36.9' C	Jessie Downs (b) (4) (b) (4)	17 Dec 2020 21:26:55

US3172467

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'Oral (Oral)'	Jessie Downs (b) (4) (b) (4)	17 Dec 2020 21:26:55

US3172467

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered empty.	Jessie Downs (b) (4) (b) (4)	17 Dec 2020 21:26:55

US3172467

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '71'	Jessie Downs (b) (4) (b) (4)	17 Dec 2020 21:26:55

US3172467

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User entered 'bpm'	System	17 Dec 2020 21:26:55

US3172467

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '13'	Jessie Downs (b) (4) (b) (4)	17 Dec 2020 21:26:55

US3172467

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User entered 'breaths/min'	System	17 Dec 2020 21:26:55

US3172467

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:47

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '135'	Jessie Downs (b) (4) (b) (4)	17 Dec 2020 21:26:55

US3172467

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User entered 'mmHg'	System	17 Dec 2020 21:26:55

US3172467

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:47

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '84'	Jessie Downs (b) (4) (b) (4)	17 Dec 2020 21:26:55

US3172467

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:47

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User entered 'mmHg'	System	17 Dec 2020 21:26:55

US3172467

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:47

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34

US3172467

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:47

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34

US3172467

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:06:47

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	17 Dec 2020 21:27:38

US3172467

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:06:47

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered empty.	Jessie Downs (b) (4) (b) (4)	17 Dec 2020 21:27:38

US3172467

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:06:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	17 Dec 2020 21:27:12

US3172467

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:06:47

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '16 Dec 2020'	Jessie Downs (b) (4) (b) (4)	17 Dec 2020 21:27:12

US3172467

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:06:47

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '12:28'	Jessie Downs (b) (4) (b) (4)	17 Dec 2020 21:27:12

US3172467

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User entered '16 Dec 2020 12:28'	System	17 Dec 2020 21:27:12

US3172467

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	17 Dec 2020 21:26:11

US3172467

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:06:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User entered '1'	System	17 Dec 2020 21:26:11

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[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 (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-12-21T17:59:33', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: 'd3db1cf1-589b-428f-9130-5c0cc9f6894a'	System	21 Dec 2020 23:00:29
User entered 'No (N)'	System	21 Dec 2020 23:00:29

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Have you been exposed to someone with 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 (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-12-21T17:59:45', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: 'd3db1cf1-589b-428f-9130-5c0cc9f6894a'	System	21 Dec 2020 23:00:29
User entered 'No (N)'	System	21 Dec 2020 23:00:29

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-12-21T18:00:25', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: 'd3db1cf1-589b-428f-9130-5c0cc9f6894a' User entered '21 Dec 2020 18:00:25'	System	21 Dec 2020 23:00:29
	System	21 Dec 2020 23:00:29

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '18 Dec 2020 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '22 Dec 2020 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[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 (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-12-25T00:06:19', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '47199b0b-5537-4bf0-8629-5669623d22f3'	System	25 Dec 2020 05:06:30
User entered 'No (N)'	System	25 Dec 2020 05:06:30

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

Have you been exposed to someone with 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 (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-12-25T00:06:24', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '47199b0b-5537-4bf0-8629-5669623d22f3' User entered 'No (N)'	System	25 Dec 2020 05:06:30
	System	25 Dec 2020 05:06:30

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2020-12-25T00:06:28', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '47199b0b-5537-4bf0-8629-5669623d22f3' User entered '25 Dec 2020 00:06:28'	System	25 Dec 2020 05:06:30
	System	25 Dec 2020 05:06:30

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '25 Dec 2020 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '29 Dec 2020 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[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 (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2021-01-03T12:14:38', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '3f8255e1-2e25-4c96-b78d-3a21b6742041'	System	10 Jan 2021 02:23:17
User entered 'No (N)'	System	10 Jan 2021 02:23:17

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Have you been exposed to someone with 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 (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2021-01-03T12:14:42', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '3f8255e1-2e25-4c96-b78d-3a21b6742041'	System	10 Jan 2021 02:23:17
User entered 'No (N)'	System	10 Jan 2021 02:23:17

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2021-01-03T12:14:45', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '3f8255e1-2e25-4c96-b78d-3a21b6742041' User entered '03 Jan 2021 12:14:45'	System	10 Jan 2021 02:23:17
	System	10 Jan 2021 02:23:17

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '01 Jan 2021 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '05 Jan 2021 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[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 (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2021-01-09T21:23:07', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '894bc3b1-cede-4d6d-b575-999cac6872af' User entered 'No (N)'	System	10 Jan 2021 02:23:17

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Have you been exposed to someone with 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 (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2021-01-09T21:23:10', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '894bc3b1-cede-4d6d-b575-999cac6872af' User entered 'No (N)'	System	10 Jan 2021 02:23:17

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2021-01-09T21:23:14', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '894bc3b1-cede-4d6d-b575-999cac6872af' User entered '09 Jan 2021 21:23:14'	System	10 Jan 2021 02:23:17
	System	10 Jan 2021 02:23:17

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '08 Jan 2021 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '12 Jan 2021 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[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 (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2021-01-15T21:58:06', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '5f76fe3d-f2b6-409b-bca5-8fa6152dc371'	System	16 Jan 2021 02:58:25
User entered 'No (N)'	System	16 Jan 2021 02:58:25

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Have you been exposed to someone with 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 (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2021-01-15T21:58:10', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '5f76fe3d-f2b6-409b-bca5-8fa6152dc371'	System	16 Jan 2021 02:58:25
User entered 'No (N)'	System	16 Jan 2021 02:58:25

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2021-01-15T21:58:20', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '5f76fe3d-f2b6-409b-bca5-8fa6152dc371' User entered '15 Jan 2021 21:58:20'	System	16 Jan 2021 02:58:25
	System	16 Jan 2021 02:58:25

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '15 Jan 2021 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '19 Jan 2021 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[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 (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2021-01-22T01:38:01', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: 'b790ab29-1a72-4481-843a-c042bdbf4654'	System	22 Jan 2021 06:38:12
User entered 'No (N)'	System	22 Jan 2021 06:38:12

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

Have you been exposed to someone with 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 (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2021-01-22T01:37:47', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: 'b790ab29-1a72-4481-843a-c042bdbf4654'	System	22 Jan 2021 06:38:12
User entered 'No (N)'	System	22 Jan 2021 06:38:12

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2021-01-22T01:38:10', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: 'b790ab29-1a72-4481-843a-c042bdbf4654' User entered '22 Jan 2021 01:38:10'	System	22 Jan 2021 06:38:12
	System	22 Jan 2021 06:38:12

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '22 Jan 2021 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '26 Jan 2021 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[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 (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2021-01-29T19:16:35', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '999439ed-4aa7-48b4-974e-c3093ef1a53b' User entered 'No (N)'	System	30 Jan 2021 00:16:51
	System	30 Jan 2021 00:16:51

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Have you been exposed to someone with 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 (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2021-01-29T19:16:43', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '999439ed-4aa7-48b4-974e-c3093ef1a53b' User entered 'No (N)'	System	30 Jan 2021 00:16:51
	System	30 Jan 2021 00:16:51

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2021-01-29T19:16:48', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '999439ed-4aa7-48b4-974e-c3093ef1a53b' User entered '29 Jan 2021 19:16:48'	System	30 Jan 2021 00:16:51
	System	30 Jan 2021 00:16:51

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '29 Jan 2021 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '02 Feb 2021 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[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 (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2021-02-07T12:00:38', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '6b59aef3-5591-4aaa-aa59-d9844872a98c'	System	07 Feb 2021 17:01:26
User entered 'No (N)'	System	07 Feb 2021 17:01:26

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Have you been exposed to someone with 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 (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2021-02-07T12:00:42', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '6b59aef3-5591-4aaa-aa59-d9844872a98c'	System	07 Feb 2021 17:01:26
User entered 'No (N)'	System	07 Feb 2021 17:01:26

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2021-02-07T12:00:49', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '6b59aef3-5591-4aaa-aa59-d9844872a98c' User entered '07 Feb 2021 12:00:49'	System	07 Feb 2021 17:01:26
	System	07 Feb 2021 17:01:26

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '05 Feb 2021 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '09 Feb 2021 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[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 (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2021-02-13T10:31:09', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: 'b8fa7a29-0c2f-4bd6-8e46-f036ea7756f5' User entered 'No (N)'	System	13 Feb 2021 15:31:18
	System	13 Feb 2021 15:31:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Have you been exposed to someone with 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 (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2021-02-13T10:31:12', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: 'b8fa7a29-0c2f-4bd6-8e46-f036ea7756f5'	System	13 Feb 2021 15:31:18
User entered 'No (N)'	System	13 Feb 2021 15:31:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2021-02-13T10:31:15', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: 'b8fa7a29-0c2f-4bd6-8e46-f036ea7756f5'	System	13 Feb 2021 15:31:18
User entered '13 Feb 2021 10:31:15'	System	13 Feb 2021 15:31:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '12 Feb 2021 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '16 Feb 2021 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[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 (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2021-02-21T12:02:49', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '2f70ef04-7d8a-4796-bdef-f893f988800a' User entered 'No (N)'	System	23 Feb 2021 14:22:50
	System	23 Feb 2021 14:22:50

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Have you been exposed to someone with 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 (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2021-02-21T12:02:52', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '2f70ef04-7d8a-4796-bdef-f893f988800a' User entered 'No (N)'	System	23 Feb 2021 14:22:50
	System	23 Feb 2021 14:22:50

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2021-02-21T12:02:55', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '2f70ef04-7d8a-4796-bdef-f893f988800a' User entered '21 Feb 2021 12:02:55'	System	23 Feb 2021 14:22:50
	System	23 Feb 2021 14:22:50

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '19 Feb 2021 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '23 Feb 2021 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[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 (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2021-02-28T12:00:32', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: 'a918c2ed-e686-40d8-8fd5-74972b043d6f' User entered 'No (N)'	System	28 Feb 2021 17:02:17
	System	28 Feb 2021 17:02:17

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

Have you been exposed to someone with 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 (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2021-02-28T12:00:37', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: 'a918c2ed-e686-40d8-8fd5-74972b043d6f' User entered 'No (N)'	System	28 Feb 2021 17:02:17

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2021-02-28T12:00:40', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: 'a918c2ed-e686-40d8-8fd5-74972b043d6f' User entered '28 Feb 2021 12:00:40'	System	28 Feb 2021 17:02:17
	System	28 Feb 2021 17:02:17

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '26 Feb 2021 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '02 Mar 2021 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[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 (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2021-03-05T07:06:08', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: 'd061f7d7-f96d-4b23-9b6b-e78c717144bd'	System	05 Mar 2021 12:06:17
User entered 'No (N)'	System	05 Mar 2021 12:06:17

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Have you been exposed to someone with 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 (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2021-03-05T07:06:10', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: 'd061f7d7-f96d-4b23-9b6b-e78c717144bd'	System	05 Mar 2021 12:06:17
User entered 'No (N)'	System	05 Mar 2021 12:06:17

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2021-03-05T07:06:13', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: 'd061f7d7-f96d-4b23-9b6b-e78c717144bd' User entered '05 Mar 2021 07:06:13'	System	05 Mar 2021 12:06:17
	System	05 Mar 2021 12:06:17

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '05 Mar 2021 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '09 Mar 2021 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[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 (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2021-03-14T12:32:29', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: 'a24779bc-e714-4723-9a79-c503ea019763'	System	14 Mar 2021 16:32:38
User entered 'No (N)'	System	14 Mar 2021 16:32:38

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

Have you been exposed to someone with 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 (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2021-03-14T12:32:31', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: 'a24779bc-e714-4723-9a79-c503ea019763'	System	14 Mar 2021 16:32:38
User entered 'No (N)'	System	14 Mar 2021 16:32:38

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2021-03-14T12:32:34', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: 'a24779bc-e714-4723-9a79-c503ea019763' User entered '14 Mar 2021 12:32:34'	System	14 Mar 2021 16:32:38
	System	14 Mar 2021 16:32:38

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '12 Mar 2021 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '16 Mar 2021 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[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 (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2021-03-20T18:50:19-04:00', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: 'd7fde2f6-5ca8-4ded-89fd-006bd84b1e64'	System	20 Mar 2021 22:50:28
User entered 'No (N)'	System	20 Mar 2021 22:50:28

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

Have you been exposed to someone with 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 (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2021-03-20T18:50:22-04:00', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: 'd7fde2f6-5ca8-4ded-89fd-006bd84b1e64'	System	20 Mar 2021 22:50:28
User entered 'No (N)'	System	20 Mar 2021 22:50:28

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2021-03-20T18:50:25-04:00', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: 'd7fde2f6-5ca8-4ded-89fd-006bd84b1e64'	System	20 Mar 2021 22:50:28
User entered '20 Mar 2021 18:50:25'	System	20 Mar 2021 22:50:28

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '19 Mar 2021 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '23 Mar 2021 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[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 (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2021-03-28T13:22:19-04:00', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '0b58010c-e315-4da7-9948-b61e630f7d2b'	System	28 Mar 2021 17:22:28
User entered 'No (N)'	System	28 Mar 2021 17:22:28

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

Have you been exposed to someone with 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 (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2021-03-28T13:22:21-04:00', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '0b58010c-e315-4da7-9948-b61e630f7d2b'	System	28 Mar 2021 17:22:28
User entered 'No (N)'	System	28 Mar 2021 17:22:28

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2021-03-28T13:22:25-04:00', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '0b58010c-e315-4da7-9948-b61e630f7d2b' User entered '28 Mar 2021 13:22:25'	System	28 Mar 2021 17:22:28
	System	28 Mar 2021 17:22:28

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '26 Mar 2021 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '30 Mar 2021 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[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 (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2021-04-04T12:41:26-04:00', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: 'ecb563ba-3d28-4f73-b5e3-98e6d9426e33'	System	04 Apr 2021 16:41:36
User entered 'No (N)'	System	04 Apr 2021 16:41:36

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

Have you been exposed to someone with 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 (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2021-04-04T12:41:28-04:00', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: 'ecb563ba-3d28-4f73-b5e3-98e6d9426e33' User entered 'No (N)'	System	04 Apr 2021 16:41:36

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2021-04-04T12:41:31-04:00', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: 'ecb563ba-3d28-4f73-b5e3-98e6d9426e33'	System	04 Apr 2021 16:41:36
User entered '04 Apr 2021 12:41:31'	System	04 Apr 2021 16:41:36

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '02 Apr 2021 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '06 Apr 2021 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[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 (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2021-04-09T00:24:49-04:00', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '43fefb5f-8027-4a2a-9b24-7caa4ff859fd'	System	09 Apr 2021 04:24:59
User entered 'No (N)'	System	09 Apr 2021 04:24:59

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

Have you been exposed to someone with 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 (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2021-04-09T00:24:53-04:00', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '43fefb5f-8027-4a2a-9b24-7caa4ff859fd' User entered 'No (N)'	System	09 Apr 2021 04:24:59

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2021-04-09T00:24:56-04:00', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '43fefb5f-8027-4a2a-9b24-7caa4ff859fd' User entered '09 Apr 2021 00:24:56'	System	09 Apr 2021 04:24:59
	System	09 Apr 2021 04:24:59

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '09 Apr 2021 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '13 Apr 2021 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '16 Apr 2021 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '20 Apr 2021 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[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 (5A73247E-D0B2-4013-BAC5-9DCCFBF36D62)', Time: '2021-04-23T06:44:55-04:00', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '05b79d06-7dbf-4c00-97d4-0dda26497b4b'	System	23 Apr 2021 10:45:26
User entered 'No (N)'	System	23 Apr 2021 10:45:26

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Have you been exposed to someone with 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 (5A73247E-D0B2-4013-BAC5-9DCCFBF36D62)', Time: '2021-04-23T06:45:00-04:00', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '05b79d06-7dbf-4c00-97d4-0dda26497b4b' User entered 'No (N)'	System	23 Apr 2021 10:45:26

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5A73247E-D0B2-4013-BAC5-9DCCFBF36D62)', Time: '2021-04-23T06:45:20-04:00', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: '05b79d06-7dbf-4c00-97d4-0dda26497b4b'	System	23 Apr 2021 10:45:26
User entered '23 Apr 2021 06:45:20'	System	23 Apr 2021 10:45:26

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '23 Apr 2021 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '27 Apr 2021 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '30 Apr 2021 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '04 May 2021 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '07 May 2021 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '11 May 2021 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '14 May 2021 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '18 May 2021 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '21 May 2021 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '25 May 2021 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '28 May 2021 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '01 Jun 2021 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '04 Jun 2021 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '08 Jun 2021 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '11 Jun 2021 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '15 Jun 2021 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '18 Jun 2021 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '22 Jun 2021 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '25 Jun 2021 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '29 Jun 2021 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '02 Jul 2021 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '06 Jul 2021 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '09 Jul 2021 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '13 Jul 2021 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '16 Jul 2021 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '20 Jul 2021 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '23 Jul 2021 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '27 Jul 2021 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '30 Jul 2021 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '03 Aug 2021 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '06 Aug 2021 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '10 Aug 2021 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '13 Aug 2021 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '17 Aug 2021 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '20 Aug 2021 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '24 Aug 2021 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '27 Aug 2021 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '31 Aug 2021 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '03 Sep 2021 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '07 Sep 2021 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '10 Sep 2021 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '14 Sep 2021 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '17 Sep 2021 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '21 Sep 2021 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '24 Sep 2021 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '28 Sep 2021 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '01 Oct 2021 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '05 Oct 2021 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '08 Oct 2021 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '12 Oct 2021 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '15 Oct 2021 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '19 Oct 2021 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '22 Oct 2021 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '26 Oct 2021 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '29 Oct 2021 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '02 Nov 2021 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '05 Nov 2021 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '09 Nov 2021 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '12 Nov 2021 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '16 Nov 2021 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '19 Nov 2021 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '23 Nov 2021 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '26 Nov 2021 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '30 Nov 2021 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '03 Dec 2021 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '07 Dec 2021 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '10 Dec 2021 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '14 Dec 2021 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '17 Dec 2021 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '21 Dec 2021 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '24 Dec 2021 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '28 Dec 2021 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '31 Dec 2021 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '04 Jan 2022 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '07 Jan 2022 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '11 Jan 2022 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '14 Jan 2022 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '18 Jan 2022 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '21 Jan 2022 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '25 Jan 2022 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '28 Jan 2022 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '01 Feb 2022 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '04 Feb 2022 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '08 Feb 2022 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '11 Feb 2022 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '15 Feb 2022 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '18 Feb 2022 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '22 Feb 2022 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '25 Feb 2022 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '01 Mar 2022 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '04 Mar 2022 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '08 Mar 2022 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '11 Mar 2022 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '15 Mar 2022 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '18 Mar 2022 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '22 Mar 2022 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '25 Mar 2022 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '29 Mar 2022 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '01 Apr 2022 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '05 Apr 2022 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '08 Apr 2022 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '12 Apr 2022 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '15 Apr 2022 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '19 Apr 2022 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '22 Apr 2022 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '26 Apr 2022 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '29 Apr 2022 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '03 May 2022 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '06 May 2022 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '10 May 2022 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '13 May 2022 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '17 May 2022 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '20 May 2022 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '24 May 2022 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '27 May 2022 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '31 May 2022 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '03 Jun 2022 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '07 Jun 2022 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '10 Jun 2022 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '14 Jun 2022 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '17 Jun 2022 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '21 Jun 2022 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '24 Jun 2022 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '28 Jun 2022 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '01 Jul 2022 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '05 Jul 2022 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '08 Jul 2022 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '12 Jul 2022 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '15 Jul 2022 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '19 Jul 2022 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '22 Jul 2022 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '26 Jul 2022 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '29 Jul 2022 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '02 Aug 2022 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '05 Aug 2022 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '09 Aug 2022 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '12 Aug 2022 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '16 Aug 2022 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '19 Aug 2022 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '23 Aug 2022 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '26 Aug 2022 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '30 Aug 2022 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '02 Sep 2022 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '06 Sep 2022 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '09 Sep 2022 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '13 Sep 2022 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 13:23:18

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '16 Sep 2022 00:01'	System	20 Nov 2020 13:23:18

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '20 Sep 2022 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '23 Sep 2022 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '27 Sep 2022 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '30 Sep 2022 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '04 Oct 2022 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '07 Oct 2022 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '11 Oct 2022 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '14 Oct 2022 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '18 Oct 2022 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '21 Oct 2022 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '25 Oct 2022 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '28 Oct 2022 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '01 Nov 2022 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '04 Nov 2022 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '08 Nov 2022 23:59'	System	20 Nov 2020 13:23:18

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '11 Nov 2022 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '15 Nov 2022 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '18 Nov 2022 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '22 Nov 2022 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '25 Nov 2022 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '29 Nov 2022 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '02 Dec 2022 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '06 Dec 2022 23:59'	System	20 Nov 2020 13:23:18

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 13:23:18

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '09 Dec 2022 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '13 Dec 2022 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 13:23:18

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '16 Dec 2022 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '20 Dec 2022 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '23 Dec 2022 00:01'	System	20 Nov 2020 13:23:18

US3172467

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:18
Amendment Manager: User entered '27 Dec 2022 23:59'	System	20 Nov 2020 13:23:18

US3172467

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:06:47

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 22:07:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2021-02-28T12:00:52', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: 'c0fe0296-967a-482a-a103-e97f475db5f5'	System	28 Feb 2021 17:02:58
User entered 'No (N)'	System	28 Feb 2021 17:02:58

US3172467

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:06:47

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:07:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA3FFEDB-5125-41E9-B580-DB2FA4353B0B)', Time: '2021-02-28T12:00:55', User OID: 'PatientReportedOutcome (US3172467)', ODM File OID: 'c0fe0296-967a-482a-a103-e97f475db5f5'	System	28 Feb 2021 17:02:58
User entered '28 Feb 2021 12:00:55'	System	28 Feb 2021 17:02:58

US3172467

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	15 Jan 2021 16:24:39

US3172467

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '14 Jan 2021'	Jessie Downs (b) (4) (b) (4)	15 Jan 2021 16:24:39

US3172467

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	15 Jan 2021 16:24:39

US3172467

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered empty.	Jessie Downs (b) (4) (b) (4)	15 Jan 2021 16:24:39

US3172467

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	15 Jan 2021 16:24:57

US3172467

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:06:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:34
User entered 'I'	System	15 Jan 2021 16:24:57

US3172467

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:07:17
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	23 Feb 2021 14:43:38
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	19 Feb 2021 16:05:08

US3172467

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:07:17
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	23 Feb 2021 14:43:38
User entered '18 Feb 2021'	Jessie Downs (b) (4) (b) (4)	19 Feb 2021 16:05:08

US3172467

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:07:17
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	23 Feb 2021 14:43:38
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	19 Feb 2021 16:05:08

US3172467

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:07:17
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	23 Feb 2021 14:43:38
User entered empty.	Jessie Downs (b) (4) (b) (4)	19 Feb 2021 16:05:08

US3172467

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:07:17
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	23 Feb 2021 14:43:32
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	19 Feb 2021 16:05:12

US3172467

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:06:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:07:17
User entered 'I'	System	19 Feb 2021 16:05:12

US3172467

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:07:17
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:45:20
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	23 Mar 2021 14:06:22

US3172467

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:47

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:07:17
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:45:20
User entered '18 Mar 2021'	Mariete Rendon (b) (4) (b) (4)	23 Mar 2021 14:06:22

US3172467

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:07:17
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:45:20
User entered 'Contact Made (CONTACT MADE)'	Mariete Rendon (b) (4) (b) (4)	23 Mar 2021 14:06:22

US3172467

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:07:17
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:45:20
User entered empty.	Mariete Rendon (b) (4) (b) (4)	23 Mar 2021 14:06:22

US3172467

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:07:17
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:45:20
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Mar 2021 14:06:40
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Mar 2021 14:06:40
User entered 'Yes (Y)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	23 Mar 2021 14:06:40
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Mar 2021 14:05:29
User entered empty.	Mariete Rendon (b) (4) (b) (4)	23 Mar 2021 14:05:29

US3172467

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:06:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:07:17
User entered '1'	System	23 Mar 2021 14:06:40
User entered empty.	System	23 Mar 2021 14:05:29

US3172467

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:45:20
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	19 Apr 2021 20:27:45

US3172467

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:45:20
User entered '19 Apr 2021'	Jessie Downs (b) (4) (b) (4)	19 Apr 2021 20:27:45

US3172467

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:45:20
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	19 Apr 2021 20:27:45

US3172467

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:06:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:45:20
User entered empty.	Jessie Downs (b) (4) (b) (4)	19 Apr 2021 20:27:45

US3172467

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:45:20
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	19 Apr 2021 20:27:49

US3172467

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:06:47

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Apr 2021 20:27:49

US3172467

Folder: Unscheduled 02 Dec 2020

Form: Unscheduled Visit Assessment

Generated On: 11 Aug 2021 22:06:47

[Visit Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:29:32
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '02 Dec 2020'	Jessie Downs (b) (4) (b) (4)	02 Dec 2020 22:17:00

US3172467

Folder: Unscheduled 02 Dec 2020

Form: Unscheduled Visit Assessment

Generated On: 11 Aug 2021 22:06:47

[Physical Exam](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:29:32
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'I'	Jessie Downs (b) (4) (b) (4)	02 Dec 2020 22:17:00

US3172467

Folder: Unscheduled 02 Dec 2020

Form: Unscheduled Visit Assessment

Generated On: 11 Aug 2021 22:06:47

[Vital Signs](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:29:32
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'I'	Jessie Downs (b) (4) (b) (4)	02 Dec 2020 22:17:00

US3172467

Folder: **Unscheduled 02 Dec 2020**

Form: **Unscheduled Visit Assessment**

Generated On: **11 Aug 2021 22:06:47**

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:29:32
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '0'	Jessie Downs (b) (4) (b) (4)	02 Dec 2020 22:17:00

US3172467

Folder: Unscheduled 02 Dec 2020

Form: Unscheduled Visit Assessment

Generated On: 11 Aug 2021 22:06:47

[Pregnancy Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:29:32
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '0'	Jessie Downs (b) (4) (b) (4)	02 Dec 2020 22:17:00

US3172467

Folder: Unscheduled 02 Dec 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:30:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	02 Dec 2020 22:17:43

US3172467

Folder: Unscheduled 02 Dec 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:30:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '02 Dec 2020'	Jessie Downs (b) (4) (b) (4)	02 Dec 2020 22:17:43

US3172467

Folder: Unscheduled 02 Dec 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:30:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '09:30'	Jessie Downs (b) (4) (b) (4)	02 Dec 2020 22:17:43

US3172467

Folder: Unscheduled 02 Dec 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:30:10
User entered '02 Dec 2020 09:30'	System	02 Dec 2020 22:17:43

US3172467

Folder: Unscheduled 02 Dec 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:30:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered missing code ND - Not Done.	Jessie Downs (b) (4) (b) (4)	02 Dec 2020 22:17:43

US3172467

Folder: Unscheduled 02 Dec 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:30:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered empty.	Jessie Downs (b) (4) (b) (4)	02 Dec 2020 22:17:43

US3172467

Folder: Unscheduled 02 Dec 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:30:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered empty.	Jessie Downs (b) (4) (b) (4)	02 Dec 2020 22:17:43

US3172467

Folder: Unscheduled 02 Dec 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:30:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '67'	Jessie Downs (b) (4) (b) (4)	02 Dec 2020 22:17:43

US3172467

Folder: Unscheduled 02 Dec 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:30:10
User entered 'bpm'	System	02 Dec 2020 22:17:43

US3172467

Folder: Unscheduled 02 Dec 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:30:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '14'	Jessie Downs (b) (4) (b) (4)	02 Dec 2020 22:17:43

US3172467

Folder: Unscheduled 02 Dec 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:30:10
User entered 'breaths/min'	System	02 Dec 2020 22:17:43

US3172467

Folder: Unscheduled 02 Dec 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:47

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:30:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '126'	Jessie Downs (b) (4) (b) (4)	02 Dec 2020 22:17:43

US3172467

Folder: **Unscheduled 02 Dec 2020**

Form: **Vital Signs**

Generated On: **11 Aug 2021 22:06:47**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:30:10
User entered 'mmHg'	System	02 Dec 2020 22:17:43

US3172467

Folder: Unscheduled 02 Dec 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:47

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:30:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '73'	Jessie Downs (b) (4) (b) (4)	02 Dec 2020 22:17:43

US3172467

Folder: Unscheduled 02 Dec 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:47

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:30:10
User entered 'mmHg'	System	02 Dec 2020 22:17:43

US3172467

Folder: Unscheduled 02 Dec 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:47

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:30:10

US3172467

Folder: Unscheduled 02 Dec 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:06:47

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:30:10

US3172467

Folder: Unscheduled 02 Dec 2020

Form: Physical Examination

Generated On: 11 Aug 2021 22:06:47

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:30:23
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	02 Dec 2020 22:17:57

US3172467

Folder: Unscheduled 02 Dec 2020

Form: Physical Examination

Generated On: 11 Aug 2021 22:06:47

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:30:23
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '02 Dec 2020'	Jessie Downs (b) (4) (b) (4)	02 Dec 2020 22:17:57

US3172467

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:06:47

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:02:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	05 Nov 2020 22:24:20
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:44:44

US3172467

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:06:47

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:52:15
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 20:40:19
User entered	System	06 Nov 2020 20:39:46
'USA-US118-2020-mRNA-1273-P301000008'		
User entered 'New'	(b) (4), (b) (6)	06 Nov 2020 20:39:46

US3172467

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:06:47

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:52:15
	(b) (4)	
User closed query 'PV Query: Since the subject was asymptomatic, please update the reported event term accordingly.' (Site from Safety).	(b) (4), (b) (6)	30 Nov 2020 17:23:53
Query 'PV Query: Since the subject was asymptomatic, please update the reported event term accordingly.' answered with 'A/E states symptomatic. Please advise?' (Site from Safety).	Mariete Rendon (b) (4)	20 Nov 2020 21:15:57
	(b) (4)	
User opened query 'PV Query: Since the subject was asymptomatic, please update the reported event term accordingly.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 14:53:54
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 06:21:31
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 06:21:31
	(b) (4)	
Data point term sent to Coder	System	05 Nov 2020 22:25:56
User entered 'COVID 19 SYMPTOMATIC'	Jessie Downs (b) (4)	05 Nov 2020 22:25:35
	(b) (4)	

US3172467

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:06:47

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	05 Nov 2020 22:25:35

US3172467

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:06:47

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	05 Nov 2020 22:25:35

US3172467

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:06:47

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	05 Nov 2020 22:25:35

US3172467

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:06:47

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '29 Oct 2020'	Jessie Downs (b) (4) (b) (4)	05 Nov 2020 22:25:35

US3172467

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:06:47

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:52:15
	(b) (4)	
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	05 Nov 2020 22:25:48
User entered empty; reason for change Data Entry Error	Jessie Downs (b) (4)	05 Nov 2020 22:25:48
	(b) (4)	
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	05 Nov 2020 22:25:35
User entered '18:00'	Jessie Downs (b) (4)	05 Nov 2020 22:25:35
	(b) (4)	

US3172467

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:06:47

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 22:25:48
User entered '29 Oct 2020 18:00'	System	05 Nov 2020 22:25:35

US3172467

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:06:47

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:52:15
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Mariete Rendon (b) (4)	20 Nov 2020 21:14:51
	(b) (4)	
User entered 'Yes (Y)'	Jessie Downs (b) (4)	05 Nov 2020 22:25:35
	(b) (4)	

US3172467

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:06:47

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '7 Nov 2020' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	20 Nov 2020 21:14:51
Query 'PV Query: Please provide the event end date (when symptoms have resolved).' canceled (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 14:55:22
User opened query 'PV Query: Please provide the event end date (when symptoms have resolved).' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 14:53:15
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Nov 2020 22:25:35

US3172467

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:06:47

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Nov 2020 22:25:35

US3172467

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:06:47

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date (when symptoms have resolved). ' canceled (Site from Safety).	(b) (4), (b) (6)	07 Dec 2020 20:21:11
User opened query 'PV Query: Please provide the event end date (when symptoms have resolved). ' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 19:27:19
User entered empty.	System	05 Nov 2020 22:25:35

US3172467

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:06:47

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:52:15
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Jessie Downs (b) (4)	05 Nov 2020 22:25:35
	(b) (4)	

US3172467

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:06:47

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	05 Nov 2020 22:25:35

US3172467

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:06:47

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '0'	Jessie Downs (b) (4) (b) (4)	05 Nov 2020 22:25:35

US3172467

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:06:47

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '0'	Jessie Downs (b) (4) (b) (4)	05 Nov 2020 22:25:35

US3172467

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:06:47

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '0'	Jessie Downs (b) (4) (b) (4)	05 Nov 2020 22:25:35

US3172467

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:06:47

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Nov 2020 22:25:35

US3172467

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:06:47

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Nov 2020 22:25:35

US3172467

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:06:47

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Nov 2020 22:25:35

US3172467

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:06:47

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Nov 2020 22:25:35

US3172467

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:06:47

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '0'	Jessie Downs (b) (4) (b) (4)	05 Nov 2020 22:25:35

US3172467

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:06:47

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '0'	Jessie Downs (b) (4) (b) (4)	05 Nov 2020 22:25:35

US3172467

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:06:47

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '0'	Jessie Downs (b) (4) (b) (4)	05 Nov 2020 22:25:35

US3172467

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:06:47

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'Not Related (NOT RELATED)'	Jessie Downs (b) (4) (b) (4)	05 Nov 2020 22:25:35

US3172467

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:06:47

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'Not Related (NOT RELATED)'	Jessie Downs (b) (4) (b) (4)	05 Nov 2020 22:25:35

US3172467

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:06:47

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:52:15
	(b) (4)	
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	07 Dec 2020 02:45:46
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered with 'Discontinuation page updated to state due to COVID positive.' (Site from System).	Mariete Rendon (b) (4)	30 Nov 2020 13:59:18
	(b) (4)	
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	30 Nov 2020 13:57:58
User closed query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 16:16:30
Query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn.' answered with 'Data was updated.' (Site from Safety).	Jessie Downs (b) (4)	13 Nov 2020 18:15:47
	(b) (4)	
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Jessie Downs (b) (4)	13 Nov 2020 18:15:25
	(b) (4)	
User opened query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 19:28:03
User entered 'Not Applicable (NOT APPLICABLE)'	Jessie Downs (b) (4)	05 Nov 2020 22:25:35
	(b) (4)	

US3172467

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:06:47

None

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '0'	Jessie Downs (b) (4) (b) (4)	05 Nov 2020 22:25:35

US3172467

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:06:47

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '1'	Jessie Downs (b) (4) (b) (4)	05 Nov 2020 22:25:35

US3172467

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:06:47

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '0'	Jessie Downs (b) (4) (b) (4)	05 Nov 2020 22:25:35

US3172467

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:06:47

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User closed query 'PV Query: Please provide the final event outcome, when available. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	30 Nov 2020 17:24:00
Query 'PV Query: Please provide the final event outcome, when available. If resolution is expected, please keep query open until achieved.' answered with 'Data updated' (Site from Safety).	Mariete Rendon (b) (4) (b) (4)	20 Nov 2020 21:25:48
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	20 Nov 2020 21:14:51
User opened query 'PV Query: Please provide the final event outcome, when available. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 14:53:29
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Jessie Downs (b) (4) (b) (4)	05 Nov 2020 22:25:35

US3172467

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:06:47

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Nov 2020 22:25:35

US3172467

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:06:47

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:52:15
	(b) (4)	
User closed query 'PV Query: Per the answered queries, the subject was asymptomatic and denied symptoms; however the event term was reported as symptomatic. Please confirm which is correct. If the subject did not experience any symptoms, please consider removing this as an event. IF the subject did experience symptoms, please complete the assessment logs.' (Site from Safety).	(b) (4), (b) (6)	08 Dec 2020 16:54:25
Query 'PV Query: Per the answered queries, the subject was asymptomatic and denied symptoms; however the event term was reported as symptomatic. Please confirm which is correct. If the subject did not experience any symptoms, please consider removing this as an event. IF the subject did experience symptoms, please complete the assessment logs.' answered with 'Subject 2467 baseline Nasal swab test came back COVID +, however, at this time subject was asymptomatic. On 29OCT2020 subject developed symptoms for COVID was taken via rescue to the hospital and was discharged from hospital with treatment. Data correct as is.' (Site from Safety).	Mariete Rendon (b) (4)	07 Dec 2020 20:26:33
	(b) (4)	
User opened query 'PV Query: Per the answered queries, the subject was asymptomatic and denied symptoms; however the event term was reported as symptomatic. Please confirm which is correct. If the subject did not experience any symptoms, please consider removing this as an event. IF the subject did experience symptoms, please complete the assessment logs.' (Site from Safety).	(b) (4), (b) (6)	07 Dec 2020 20:22:11
Query 'Per the answered queries, the subject was asymptomatic and denied symptoms; however the event term was reported as symptomatic. Please confirm which is correct. If the subject did not experience any symptoms, please consider removing this as an event. IF the subject did experience symptoms, please complete the assessment logs.' canceled (Site from Safety).	(b) (4), (b) (6)	07 Dec 2020 20:21:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:06:47

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per the answered queries, the subject was asymptomatic and denied symptoms; however the event term was reported as symptomatic. Please confirm which is correct. If the subject did not experience any symptoms, please consider removing this as an event. IF the subject did experience symptoms, please complete the assessment logs.' (Site from Safety).	(b) (4), (b) (6)	07 Dec 2020 20:21:45
User closed query 'PV Query: Please provide the final event outcome, when available. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 16:16:42
User closed query 'PV Query: Please confirm if the subject had any known exposure to COVID-19 or risk factors.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 16:16:39
User closed query 'PV Query: Please complete the Covid-19 Assessments tab, including results of Covid-19 diagnostic test, symptoms log, and severity assessment.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 16:16:36
Query 'PV Query: Please complete the Covid-19 Assessments tab, including results of Covid-19 diagnostic test, symptoms log, and severity assessment.' answered with 'Subject reported asymptomatic, denies any symptoms of SARS.' (Site from Safety).	Jessie Downs (b) (4) (b) (4)	13 Nov 2020 18:22:24
Query 'PV Query: Please confirm if the subject had any known exposure to COVID-19 or risk factors.' answered with 'Medical records will be requested.' (Site from Safety).	Jessie Downs (b) (4) (b) (4)	13 Nov 2020 18:21:42
Query 'PV Query: Please provide the final event outcome, when available. If resolution is expected, please keep query open until achieved.' answered with 'Subject reported asymptomatic denies any symptoms of SARS. Medical records will be requested. Subject was not admitted.' (Site from Safety).	Jessie Downs (b) (4) (b) (4)	13 Nov 2020 18:21:22
User opened query 'PV Query: Please provide the final event outcome, when available. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 19:28:35

US3172467

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:06:47

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please confirm if the subject had any known exposure to COVID-19 or risk factors. ' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 19:28:18
User opened query 'PV Query: Please complete the Covid-19 Assessments tab, including results of Covid-19 diagnostic test, symptoms log, and severity assessment. ' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 19:27:44
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Nov 2020 22:25:35

US3172467

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:06:47

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	05 Nov 2020 22:25:35

US3172467

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:06:47

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Nov 2020 22:25:35

US3172467

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:06:47

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:47

US3172467

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:06:47

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:47
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Skin structures and soft tissue infections, PT: Folliculitis, LLT: Folliculitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Nov 2020 07:05:06
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Nov 2020 07:05:06
Data point term sent to Coder	System	25 Nov 2020 21:05:51
User entered 'foliiculitis neck hairline'	Mariete Rendon (b) (4) (b) (4)	25 Nov 2020 21:05:15

US3172467

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:06:47

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:47
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	25 Nov 2020 21:05:15

US3172467

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:06:47

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:47
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	25 Nov 2020 21:05:15

US3172467

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:06:47

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:47
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	25 Nov 2020 21:05:15

US3172467

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:06:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:47
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '16 Nov 2020'	Mariete Rendon (b) (4) (b) (4)	25 Nov 2020 21:05:15

US3172467

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:06:47

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:47
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered empty.	Mariete Rendon (b) (4) (b) (4)	25 Nov 2020 21:05:15

US3172467

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:06:47

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:47
User entered empty.	System	25 Nov 2020 21:05:15

US3172467

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:06:47

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:47
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	02 Dec 2020 22:23:58
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	25 Nov 2020 21:05:15

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:06:47

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:47
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '02 Dec 2020' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	02 Dec 2020 22:23:58
User entered empty.	Mariete Rendon (b) (4) (b) (4)	25 Nov 2020 21:05:15

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:06:47

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:47
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	02 Dec 2020 22:24:06
User entered empty; reason for change Data Entry Error	Jessie Downs (b) (4) (b) (4)	02 Dec 2020 22:24:06
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	02 Dec 2020 22:23:58
User entered '07:00' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	02 Dec 2020 22:23:58
User entered empty.	Mariete Rendon (b) (4) (b) (4)	25 Nov 2020 21:05:15

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:06:47

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:47
User entered empty.	System	02 Dec 2020 22:24:06
User entered '02 Dec 2020 07:00'	System	02 Dec 2020 22:23:58
User entered empty.	System	25 Nov 2020 21:05:15

US3172467

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:06:47

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:47
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'Grade 1/Mild (Grade 1/Mild)'	Mariete Rendon (b) (4) (b) (4)	25 Nov 2020 21:05:15

US3172467

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:06:47

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:47
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	25 Nov 2020 21:05:15

US3172467

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:06:47

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:47
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '0'	Mariete Rendon (b) (4) (b) (4)	25 Nov 2020 21:05:15

US3172467

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:06:47

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:47
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '0'	Mariete Rendon (b) (4) (b) (4)	25 Nov 2020 21:05:15

US3172467

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:06:47

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:47
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '0'	Mariete Rendon (b) (4) (b) (4)	25 Nov 2020 21:05:15

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:06:47

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:47
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered empty.	Mariete Rendon (b) (4) (b) (4)	25 Nov 2020 21:05:15

US3172467

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:06:47

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:47
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered empty.	Mariete Rendon (b) (4) (b) (4)	25 Nov 2020 21:05:15

US3172467

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:06:47

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:47
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered empty.	Mariete Rendon (b) (4) (b) (4)	25 Nov 2020 21:05:15

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:06:47

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:47
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered empty.	Mariete Rendon (b) (4) (b) (4)	25 Nov 2020 21:05:15

US3172467

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:06:47

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:47
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '0'	Mariete Rendon (b) (4) (b) (4)	25 Nov 2020 21:05:15

US3172467

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:06:47

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:47
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '0'	Mariete Rendon (b) (4) (b) (4)	25 Nov 2020 21:05:15

US3172467

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:06:47

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:47
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '0'	Mariete Rendon (b) (4) (b) (4)	25 Nov 2020 21:05:15

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:06:47

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:47
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'Not Related (NOT RELATED)'	Mariete Rendon (b) (4) (b) (4)	25 Nov 2020 21:05:15

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:06:47

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:47
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'Not Related (NOT RELATED)'	Mariete Rendon (b) (4) (b) (4)	25 Nov 2020 21:05:15

US3172467

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:06:47

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:47
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'Not Applicable (NOT APPLICABLE)'	Mariete Rendon (b) (4) (b) (4)	25 Nov 2020 21:05:15

US3172467

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:06:47

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:47
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '0'	Mariete Rendon (b) (4) (b) (4)	25 Nov 2020 21:05:15

US3172467

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:06:47

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:47
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'I'	Mariete Rendon (b) (4) (b) (4)	25 Nov 2020 21:05:15

US3172467

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:06:47

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:47
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '0'	Mariete Rendon (b) (4) (b) (4)	25 Nov 2020 21:05:15

US3172467

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:06:47

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:47
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	02 Dec 2020 22:23:58
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Mariete Rendon (b) (4) (b) (4)	25 Nov 2020 21:05:15

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:06:47

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:47
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered empty.	Mariete Rendon (b) (4) (b) (4)	25 Nov 2020 21:05:15

US3172467

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:06:47

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:47
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered empty.	Mariete Rendon (b) (4) (b) (4)	25 Nov 2020 21:05:15

US3172467

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:06:47

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:47
User entered '0'	System	25 Nov 2020 21:05:15

US3172467

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:06:47

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:47
User entered 'I'	System	25 Nov 2020 21:05:15

US3172467

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:06:47

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:47

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:06:47

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:02:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	05 Nov 2020 22:26:46
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:44:58

US3172467

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:06:47

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:52:15
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 22:29:31
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 22:29:31
	(b) (4)	
Data point term sent to Coder	System	05 Nov 2020 22:29:01
User entered 'TYLENOL'	Jessie Downs (b) (4)	05 Nov 2020 22:28:20
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:06:47

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	05 Nov 2020 22:28:20

US3172467

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:06:47

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'COVID SYMPTOMS - FEVER'	Jessie Downs (b) (4) (b) (4)	05 Nov 2020 22:28:20

US3172467

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:06:47

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '500'	Jessie Downs (b) (4) (b) (4)	05 Nov 2020 22:28:20

US3172467

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:06:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'mg (mg)'	Jessie Downs (b) (4) (b) (4)	05 Nov 2020 22:28:20

US3172467

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:06:47

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Nov 2020 22:28:20

US3172467

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:06:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'as needed (PRN)'	Jessie Downs (b) (4) (b) (4)	05 Nov 2020 22:28:20

US3172467

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:06:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Nov 2020 22:28:20

US3172467

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:06:47

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'Oral (ORAL)'	Jessie Downs (b) (4) (b) (4)	05 Nov 2020 22:28:20

US3172467

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:06:47

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Nov 2020 22:28:20

US3172467

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:06:47

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '29 Oct 2020'	Jessie Downs (b) (4) (b) (4)	05 Nov 2020 22:28:20

US3172467

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:06:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '0'	Jessie Downs (b) (4) (b) (4)	05 Nov 2020 22:28:20

US3172467

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:06:47

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:52:15
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4)	02 Dec 2020 22:25:01
User entered 'Yes (Y)'	Jessie Downs (b) (4)	05 Nov 2020 22:28:20
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:52:15
	(b) (4)	
User entered '05 Nov 2020' reason for change: Data Entry Error	Jessie Downs (b) (4)	02 Dec 2020 22:25:01
User entered empty.	(b) (4)	
	Jessie Downs (b) (4)	05 Nov 2020 22:28:20
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:06:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	05 Nov 2020 22:28:20

US3172467

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:06:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 22:28:20

US3172467

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:06:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 22:28:20

US3172467

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:06:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 22:28:20

US3172467

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:06:47

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:36:50
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 06:24:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 06:24:30
Data point term sent to Coder	System	05 Nov 2020 22:30:03
User entered 'azithromycin'	Jessie Downs (b) (4) (b) (4)	05 Nov 2020 22:29:22

US3172467

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:06:47

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:36:50
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	05 Nov 2020 22:29:22

US3172467

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:06:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:36:50
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'COVID 19'	Jessie Downs (b) (4) (b) (4)	05 Nov 2020 22:29:22

US3172467

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:06:47

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:36:50
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '250'	Jessie Downs (b) (4) (b) (4)	05 Nov 2020 22:29:22

US3172467

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:06:47

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:36:50
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'mg (mg)'	Jessie Downs (b) (4) (b) (4)	05 Nov 2020 22:29:22

US3172467

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:06:47

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:36:50
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Nov 2020 22:29:22

US3172467

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:06:47

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:36:50
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'once daily (QD)'	Jessie Downs (b) (4) (b) (4)	05 Nov 2020 22:29:22

US3172467

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:06:47

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:36:50
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Nov 2020 22:29:22

US3172467

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:06:47

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:36:50
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'Oral (ORAL)'	Jessie Downs (b) (4) (b) (4)	05 Nov 2020 22:29:22

US3172467

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:06:47

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:36:50
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Nov 2020 22:29:22

US3172467

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:06:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:36:50
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '30 Oct 2020'	Jessie Downs (b) (4) (b) (4)	05 Nov 2020 22:29:22

US3172467

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:06:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:36:50
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '0'	Jessie Downs (b) (4) (b) (4)	05 Nov 2020 22:29:22

US3172467

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:06:47

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:36:50
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:52:15
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4)	02 Dec 2020 22:25:19
	(b) (4)	
User entered 'Yes (Y)'	Jessie Downs (b) (4)	05 Nov 2020 22:29:22
	(b) (4)	

US3172467

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:36:50
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:52:15
	(b) (4)	
User entered '05 Nov 2020' reason for change: Data Entry Error	Jessie Downs (b) (4)	02 Dec 2020 22:25:19
User entered empty.	(b) (4)	
	Jessie Downs (b) (4)	05 Nov 2020 22:29:22
	(b) (4)	

US3172467

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:06:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:36:50
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	05 Nov 2020 22:29:22

US3172467

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:06:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:36:50
User entered '1'	System	05 Nov 2020 22:29:22

US3172467

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:06:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:36:50
User entered '1'	System	05 Nov 2020 22:29:22

US3172467

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:06:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:36:50
User entered '804 (804)'	System	05 Nov 2020 22:29:22

US3172467

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:06:47

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFALLEXIN, PRODUCTSYNONYM: CEPHALEXIN [CEFALEXIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Nov 2020 22:17:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Nov 2020 22:17:58
Data point term sent to Coder	System	25 Nov 2020 21:09:57
User entered 'Cephalexin'	Mariete Rendon (b) (4) (b) (4)	25 Nov 2020 21:09:48

US3172467

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:06:47

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	25 Nov 2020 21:09:48

US3172467

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:06:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'neck hairline folliculitis'	Mariete Rendon (b) (4) (b) (4)	25 Nov 2020 21:09:48

US3172467

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:06:47

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '500'	Mariete Rendon (b) (4) (b) (4)	25 Nov 2020 21:09:48

US3172467

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:06:47

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'mg (mg)'	Mariete Rendon (b) (4) (b) (4)	25 Nov 2020 21:09:48

US3172467

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:06:47

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered empty.	Mariete Rendon (b) (4) (b) (4)	25 Nov 2020 21:09:48

US3172467

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:06:47

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'twice daily (BID)'	Mariete Rendon (b) (4) (b) (4)	25 Nov 2020 21:09:48

US3172467

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:06:47

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered empty.	Mariete Rendon (b) (4) (b) (4)	25 Nov 2020 21:09:48

US3172467

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:06:47

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'Oral (ORAL)'	Mariete Rendon (b) (4) (b) (4)	25 Nov 2020 21:09:48

US3172467

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:06:47

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered empty.	Mariete Rendon (b) (4) (b) (4)	25 Nov 2020 21:09:48

US3172467

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:06:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '19 Nov 2020'	Mariete Rendon (b) (4) (b) (4)	25 Nov 2020 21:09:48

US3172467

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:06:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '0'	Mariete Rendon (b) (4) (b) (4)	25 Nov 2020 21:09:48

US3172467

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:06:47

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:41:46
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:52:15
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4)	02 Dec 2020 22:25:40
	(b) (4)	
User entered 'Yes (Y)'	Mariete Rendon (b) (4)	25 Nov 2020 21:09:48
	(b) (4)	

US3172467

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '02 Dec 2020' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	02 Dec 2020 22:25:40
User entered empty.	Mariete Rendon (b) (4) (b) (4)	25 Nov 2020 21:09:48

US3172467

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:06:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:41:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	25 Nov 2020 21:09:48

US3172467

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:06:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:41:46
User entered '2'	System	25 Nov 2020 21:09:48

US3172467

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:06:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:41:46
User entered '1'	System	25 Nov 2020 21:09:48

US3172467

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:06:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:41:46
User entered '804 (804)'	System	25 Nov 2020 21:09:48

US3172467

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:06:47

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 21:45:04

US3172467

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:06:47

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered '26 Nov 2020'	Mariete Rendon (b) (4) (b) (4)	30 Nov 2020 13:57:58

US3172467

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:06:47

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'Due to SARS-COV-2 (COVID)'	Mariete Rendon (b) (4) (b) (4)	30 Nov 2020 13:57:58

US3172467

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:06:47

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)	28 Apr 2021 01:44:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered empty.	Mariete Rendon (b) (4) (b) (4)	30 Nov 2020 13:57:58

US3172467

Folder: SAE USA-US118-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:47

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:52:15
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 20:40:30
User entered		
'USA-US118-2020-MRNA-1273-P301000008'	System	06 Nov 2020 20:39:46

US3172467

Folder: SAE USA-US118-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:47

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:52:15
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 20:40:30
User entered 'No (N)'	System	06 Nov 2020 20:39:46

US3172467

Folder: SAE USA-US118-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:47

Death

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:52:15
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 20:40:30
User entered 'No (N)'	System	06 Nov 2020 20:39:46

US3172467

Folder: SAE USA-US118-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:47

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:52:15
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 20:40:30
User entered 'No (N)'	System	06 Nov 2020 20:39:46

US3172467

Folder: SAE USA-US118-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:47

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:52:15
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 20:40:30
User entered 'No (N)'	System	06 Nov 2020 20:39:46

US3172467

Folder: SAE USA-US118-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:47

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:52:15
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 20:40:30
User entered 'No (N)'	System	06 Nov 2020 20:39:46

US3172467

Folder: SAE USA-US118-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:47

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:52:15
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 20:40:30
User entered 'No (N)'	System	06 Nov 2020 20:39:46

US3172467

Folder: SAE USA-US118-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:47

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:52:15
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 20:40:30
User entered 'No (N)'	System	06 Nov 2020 20:39:46

US3172467

Folder: SAE USA-US118-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:47

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:52:15
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 20:40:30
User entered 'Mark'	System	06 Nov 2020 20:39:46

US3172467

Folder: SAE USA-US118-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:47

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:52:15
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 20:40:30
User entered 'Kutner'	System	06 Nov 2020 20:39:46

US3172467

Folder: SAE USA-US118-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:47

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:52:15
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 20:40:30
User entered 'FL'	System	06 Nov 2020 20:39:46

US3172467

Folder: SAE USA-US118-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:47

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:52:15
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 16:16:52
User entered 'US'	System	06 Nov 2020 20:40:39

US3172467

Folder: SAE USA-US118-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:47

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:52:15
	(b) (4)	
User entered '4'	System	08 Dec 2020 18:05:34
User entered '3'	System	30 Nov 2020 17:24:19
User entered '2'	System	16 Nov 2020 16:17:03
User entered '1'	System	06 Nov 2020 20:40:39

US3172467

Folder: SAE USA-US118-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:47

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:52:15
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 20:40:30
User entered 'USA-US118-2020-MRNA-1273-P301000008'	System	06 Nov 2020 20:39:46

US3172467

Folder: SAE USA-US118-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:47

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:52:15
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 20:40:30
User entered 'No (N)'	System	06 Nov 2020 20:39:46

US3172467

Folder: SAE USA-US118-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:47

Death

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:52:15
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 20:40:30
User entered 'No (N)'	System	06 Nov 2020 20:39:46

US3172467

Folder: SAE USA-US118-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:47

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:52:15
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 20:40:30
User entered 'No (N)'	System	06 Nov 2020 20:39:46

US3172467

Folder: SAE USA-US118-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:47

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:52:15
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 20:40:30
User entered 'No (N)'	System	06 Nov 2020 20:39:46

US3172467

Folder: SAE USA-US118-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:47

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:52:15
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 20:40:30
User entered 'No (N)'	System	06 Nov 2020 20:39:46

US3172467

Folder: SAE USA-US118-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:47

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:52:15
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 20:40:30
User entered 'No (N)'	System	06 Nov 2020 20:39:46

US3172467

Folder: SAE USA-US118-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:47

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:52:15
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 20:40:30
User entered 'No (N)'	System	06 Nov 2020 20:39:46

US3172467

Folder: SAE USA-US118-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:47

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:52:15
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 20:40:30
User entered 'Mark'	System	06 Nov 2020 20:39:46

US3172467

Folder: SAE USA-US118-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:47

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:52:15
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 20:40:30
User entered 'Kutner'	System	06 Nov 2020 20:39:46

US3172467

Folder: SAE USA-US118-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:47

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:52:15
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 20:40:30
User entered 'FL'	System	06 Nov 2020 20:39:46

US3172467

Folder: SAE USA-US118-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:47

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:52:15
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 16:16:52
User entered 'US'	System	06 Nov 2020 20:40:39

US3172467

Folder: SAE USA-US118-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:47

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:52:15
	(b) (4)	
User entered '4'	System	08 Dec 2020 18:05:34
User entered '3'	System	30 Nov 2020 17:24:19
User entered '2'	System	16 Nov 2020 16:17:03
User entered '1'	System	06 Nov 2020 20:40:39

US3172467

Folder: SAE USA-US118-2020-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:06:47

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:52:15
	(b) (4)	
User entered '06/Nov/2020 15:40'	System	06 Nov 2020 20:40:39

US3172467

Folder: SAE USA-US118-2020-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:06:47

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 16:16:52
User entered 'I'	(b) (4), (b) (6)	06 Nov 2020 20:40:39

US3172467

Folder: SAE USA-US118-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:47

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:52:15
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 20:40:30
User entered 'USA-US118-2020-MRNA-1273-P301000008'	System	06 Nov 2020 20:39:46

US3172467

Folder: SAE USA-US118-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:47

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:52:15
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 20:40:30
User entered 'No (N)'	System	06 Nov 2020 20:39:46

US3172467

Folder: SAE USA-US118-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:47

Death

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:52:15
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 20:40:30
User entered 'No (N)'	System	06 Nov 2020 20:39:46

US3172467

Folder: SAE USA-US118-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:47

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:52:15
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 20:40:30
User entered 'No (N)'	System	06 Nov 2020 20:39:46

US3172467

Folder: SAE USA-US118-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:47

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:52:15
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 20:40:30
User entered 'No (N)'	System	06 Nov 2020 20:39:46

US3172467

Folder: SAE USA-US118-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:47

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:52:15
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 20:40:30
User entered 'No (N)'	System	06 Nov 2020 20:39:46

US3172467

Folder: SAE USA-US118-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:47

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:52:15
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 20:40:30
User entered 'No (N)'	System	06 Nov 2020 20:39:46

US3172467

Folder: SAE USA-US118-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:47

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:52:15
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 20:40:30
User entered 'No (N)'	System	06 Nov 2020 20:39:46

US3172467

Folder: SAE USA-US118-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:47

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:52:15
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 20:40:30
User entered 'Mark'	System	06 Nov 2020 20:39:46

US3172467

Folder: SAE USA-US118-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:47

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:52:15
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 20:40:30
User entered 'Kutner'	System	06 Nov 2020 20:39:46

US3172467

Folder: SAE USA-US118-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:47

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:52:15
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 20:40:30
User entered 'FL'	System	06 Nov 2020 20:39:46

US3172467

Folder: SAE USA-US118-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:47

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:52:15
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 16:16:52
User entered 'US'	System	06 Nov 2020 20:40:39

US3172467

Folder: SAE USA-US118-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:47

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:52:15
	(b) (4)	
User entered '4'	System	08 Dec 2020 18:05:34
User entered '3'	System	30 Nov 2020 17:24:19
User entered '2'	System	16 Nov 2020 16:17:03
User entered '1'	System	06 Nov 2020 20:40:39

US3172467

Folder: SAE USA-US118-2020-MRNA-1273-P301000008

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:06:47

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:52:15
	(b) (4)	
User entered '16/Nov/2020 16:17'	System	16 Nov 2020 16:17:03

US3172467

Folder: SAE USA-US118-2020-MRNA-1273-P301000008

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:06:47

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 17:24:08
User entered 'I'	(b) (4), (b) (6)	16 Nov 2020 16:17:03

US3172467

Folder: SAE USA-US118-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:47

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:52:15
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 20:40:30
User entered		
'USA-US118-2020-MRNA-1273-P301000008'	System	06 Nov 2020 20:39:46

US3172467

Folder: SAE USA-US118-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:47

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:52:15
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 20:40:30
User entered 'No (N)'	System	06 Nov 2020 20:39:46

US3172467

Folder: SAE USA-US118-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:47

Death

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:52:15
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 20:40:30
User entered 'No (N)'	System	06 Nov 2020 20:39:46

US3172467

Folder: SAE USA-US118-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:47

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:52:15
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 20:40:30
User entered 'No (N)'	System	06 Nov 2020 20:39:46

US3172467

Folder: SAE USA-US118-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:47

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:52:15
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 20:40:30
User entered 'No (N)'	System	06 Nov 2020 20:39:46

US3172467

Folder: SAE USA-US118-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:47

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:52:15
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 20:40:30
User entered 'No (N)'	System	06 Nov 2020 20:39:46

US3172467

Folder: SAE USA-US118-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:47

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:52:15
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 20:40:30
User entered 'No (N)'	System	06 Nov 2020 20:39:46

US3172467

Folder: SAE USA-US118-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:47

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:52:15
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 20:40:30
User entered 'No (N)'	System	06 Nov 2020 20:39:46

US3172467

Folder: SAE USA-US118-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:47

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:52:15
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 20:40:30
User entered 'Mark'	System	06 Nov 2020 20:39:46

US3172467

Folder: SAE USA-US118-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:47

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:52:15
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 20:40:30
User entered 'Kutner'	System	06 Nov 2020 20:39:46

US3172467

Folder: SAE USA-US118-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:47

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:52:15
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 20:40:30
User entered 'FL'	System	06 Nov 2020 20:39:46

US3172467

Folder: SAE USA-US118-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:47

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:52:15
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 16:16:52
User entered 'US'	System	06 Nov 2020 20:40:39

US3172467

Folder: SAE USA-US118-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:47

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:52:15
	(b) (4)	
User entered '4'	System	08 Dec 2020 18:05:34
User entered '3'	System	30 Nov 2020 17:24:19
User entered '2'	System	16 Nov 2020 16:17:03
User entered '1'	System	06 Nov 2020 20:40:39

US3172467

Folder: SAE USA-US118-2020-MRNA-1273-P301000008

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 22:06:47

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:52:15
	(b) (4)	
User entered '30/Nov/2020 17:24'	System	30 Nov 2020 17:24:19

US3172467

Folder: SAE USA-US118-2020-MRNA-1273-P301000008

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 22:06:47

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'I'	(b) (4), (b) (6)	30 Nov 2020 17:24:19

US3172467

Folder: SAE USA-US118-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:47

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:52:15
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 20:40:30
User entered		
'USA-US118-2020-MRNA-1273-P301000008'	System	06 Nov 2020 20:39:46

US3172467

Folder: SAE USA-US118-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:47

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:52:15
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 20:40:30
User entered 'No (N)'	System	06 Nov 2020 20:39:46

US3172467

Folder: SAE USA-US118-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:47

Death

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:52:15
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 20:40:30
User entered 'No (N)'	System	06 Nov 2020 20:39:46

US3172467

Folder: SAE USA-US118-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:47

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:52:15
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 20:40:30
User entered 'No (N)'	System	06 Nov 2020 20:39:46

US3172467

Folder: SAE USA-US118-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:47

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:52:15
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 20:40:30
User entered 'No (N)'	System	06 Nov 2020 20:39:46

US3172467

Folder: SAE USA-US118-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:47

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:52:15
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 20:40:30
User entered 'No (N)'	System	06 Nov 2020 20:39:46

US3172467

Folder: SAE USA-US118-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:47

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:52:15
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 20:40:30
User entered 'No (N)'	System	06 Nov 2020 20:39:46

US3172467

Folder: SAE USA-US118-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:47

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:52:15
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 20:40:30
User entered 'No (N)'	System	06 Nov 2020 20:39:46

US3172467

Folder: SAE USA-US118-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:47

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:52:15
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 20:40:30
User entered 'Mark'	System	06 Nov 2020 20:39:46

US3172467

Folder: SAE USA-US118-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:47

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:52:15
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 20:40:30
User entered 'Kutner'	System	06 Nov 2020 20:39:46

US3172467

Folder: SAE USA-US118-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:47

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:52:15
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 20:40:30
User entered 'FL'	System	06 Nov 2020 20:39:46

US3172467

Folder: SAE USA-US118-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:47

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:52:15
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 16:16:52
User entered 'US'	System	06 Nov 2020 20:40:39

US3172467

Folder: SAE USA-US118-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:06:47

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:52:15
	(b) (4)	
User entered '4'	System	08 Dec 2020 18:05:34
User entered '3'	System	30 Nov 2020 17:24:19
User entered '2'	System	16 Nov 2020 16:17:03
User entered '1'	System	06 Nov 2020 20:40:39

US3172467

Folder: SAE USA-US118-2020-MRNA-1273-P301000008

Form: Safety Report Form (4)

Generated On: 11 Aug 2021 22:06:47

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:52:15
	(b) (4)	
User entered '08/Dec/2020 10:05'	System	08 Dec 2020 18:05:34

US3172467

Folder: SAE USA-US118-2020-MRNA-1273-P301000008

Form: Safety Report Form (4)

Generated On: 11 Aug 2021 22:06:47

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:15
User entered 'I'	(b) (4), (b) (6)	08 Dec 2020 18:05:34