

US3172038 (Prod: Suncoast Research Group LLC - ERN-PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:34:29

All time stamps listed in this document are displayed in GMT

US3172038

Form: Participant Creation

Data signed: (b) (4) 16 Feb 2021 15:04:48

Generated On: 09 Jun 2021 15:34:29

Participant ID

US3172038

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

US3172038

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 15:04:50

Generated On: 09 Jun 2021 15:34:29

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

Visit date (dd MMM yyyy)	11 AUG 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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US3172038

Folder: Screening

Form: Demographics

Data signed: (b) (4) 16 Feb 2021 15:04:50

Generated On: 09 Jun 2021 15:34:29

Date of Birth (MMM yyyy)	(b) (6) 1986
Age	34
Age Units	YEARS
Age (Derived)	34
Sex	Female <input checked="" type="radio"/> Male <input 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

US3172038

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 16 Feb 2021 15:04:50

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Date of Informed Consent (*dd MMM yyyy*) 11 AUG 2020

Month and Year of Informed Consent (derived) AUG 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1	<input checked="" type="radio"/>
Amendment 2	<input 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

US3172038

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 16 Feb 2021 15:04:50

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3172038

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 16 Feb 2021 15:04:50

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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) 16 Feb 2021 15:04:50

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Condition	OBESE
Start date (dd MMM yyyy)	UN UNK 2018
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 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 16 Feb 2021 15:04:50

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Condition	TUBAL LIGATION
Start date (dd MMM yyyy)	UN UNK 2012
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 2012
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	JAN 2012
Stop Year (derived)	2012

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 16 Feb 2021 15:04:50

Generated On: 09 Jun 2021 15:34:29

Condition	BREAST AUGMENTATION
Start date (dd MMM yyyy)	UN UNK 2009
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 2009
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2009
Start Year (derived)	2009
Stop Month and Year (derived)	JAN 2009
Stop Year (derived)	2009

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 16 Feb 2021 15:04:50

Generated On: 09 Jun 2021 15:34:29

Condition	BREAST AUGMENTATION
Start date (dd MMM yyyy)	UN UNK 2017
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 2017
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	JAN 2017
Stop Year (derived)	2017

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 16 Feb 2021 15:04:50

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Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	11 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	09:45 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 09:45
Height (<i>xxx.x</i>)	169.0 cm
Weight (<i>xxx.x</i>)	104.7 kg
BMI (<i>xxx.x</i>)	36.65838 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 15:04:50

Generated On: 09 Jun 2021 15:34:29

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: Childbearing Potential

Data signed: (b) (4) 16 Feb 2021 15:04:50

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Date of assessment (dd MMM yyyy) 11 AUG 2020

Is the participant of childbearing potential? Yes ☐
No ☒

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

If Partner medically sterile or Other, specify _____

If Surgically sterile, date of surgery (dd MMM yyyy) UN UNK 2012

Date of surgery unknown False

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

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 16 Feb 2021 15:04:50

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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) 16 Feb 2021 15:04:50

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Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	True
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) 16 Feb 2021 15:04:50

Generated On: 09 Jun 2021 15:34:29

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

Visit date (dd MMM yyyy)	11 AUG 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	VISIT1
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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 16 Feb 2021 15:04:50

Generated On: 09 Jun 2021 15:34:29

What was the date of randomization? (dd MMM yyyy) 11 AUG 2020

What was the participant's randomization number? 102992

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 ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 16 Feb 2021 15:04:50

Generated On: 09 Jun 2021 15:34:29

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) 16 Feb 2021 15:04:50

Generated On: 09 Jun 2021 15:34:29

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)	11 AUG 2020
Time of assessment (00:00-23:59)	09:45 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 09:45
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Feb 2021 15:04:50

Generated On: 09 Jun 2021 15:34:29

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)	11 AUG 2020
Time of assessment (00:00-23:59)	12:35 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 12:35
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 15:04:50

Generated On: 09 Jun 2021 15:34:29

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 AUG 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 15:04:50

Generated On: 09 Jun 2021 15:34:29

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) 11 AUG 2020

What was the treatment time? (00:00-23:59) 12:05 (24 HR)

Treatment Date and Time (derived) 11 AUG 2020 12:05

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) 16 Feb 2021 15:04:50

Generated On: 09 Jun 2021 15:34:29

Was the sample collected? Yes ☒
No ☐

Collection date (dd MMM yyyy) 11 AUG 2020

Collection time (00:00-23:59) 11:49 (24 HR)

Collection date and time (derived) 11 AUG 2020 11:49

US3172038

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Feb 2021 15:04:50

Generated On: 09 Jun 2021 15:34:29

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

US3172038

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 15:04:50

Generated On: 09 Jun 2021 15:34:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172038

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:34:29

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 11 AUG 2020 12:41

PC Open Date & Time 11 AUG 2020 12:25

PC Close Date & Time 11 AUG 2020 14:55

US3172038

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.4 °F

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

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

PC Time Stamp	11 AUG 2020 21:26
PC Open Date & Time	11 AUG 2020 15:50
PC Close Date & Time	12 AUG 2020 11:59

US3172038

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 AUG 2020 22:03

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3172038

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 AUG 2020 19:44

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3172038

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 AUG 2020 22:33

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3172038

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 AUG 2020 23:59

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3172038

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 AUG 2020 22:41

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3172038

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 AUG 2020 05:10

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3172038

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:34:29

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

11 AUG 2020 12:41

PC Open Date & Time

11 AUG 2020 12:25

PC Close Date & Time

11 AUG 2020 14:55

US3172038

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:34:29

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

11 AUG 2020 21:26

PC Open Date & Time

11 AUG 2020 15:50

PC Close Date & Time

12 AUG 2020 11:59

US3172038

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:34:29

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

12 AUG 2020 22:03

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3172038

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:34:29

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

13 AUG 2020 19:44

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3172038

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:34:29

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

14 AUG 2020 22:34

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3172038

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:34:29

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

15 AUG 2020 23:59

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3172038

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:34:29

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

16 AUG 2020 22:41

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3172038

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:34:29

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

18 AUG 2020 05:10

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:34:29

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 ☐

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:34:29

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

No ☒

Yes ☐

PC Time stamp	11 AUG 2020 12:41
PC Open Date & Time	11 AUG 2020 12:25
PC Close Date & Time	11 AUG 2020 14:55

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:34:29

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 ☐

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:34:29

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

No ☒

Yes ☐

PC Time stamp	11 AUG 2020 21:27
PC Open Date & Time	11 AUG 2020 15:50
PC Close Date & Time	12 AUG 2020 11:59

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:34:29

Yes <input type="checkbox"/>	
PC Time stamp	12 AUG 2020 22:03
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:34:29

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 ☒

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:34:29

Yes <input type="checkbox"/>	
PC Time stamp	13 AUG 2020 19:44
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:34:29

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

50 of 4549

EAB) (1725)

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:34:29

Yes <input type="checkbox"/>	
PC Time stamp	14 AUG 2020 22:34
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:34:29

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

52 of 4549

EAB) (1725)

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:34:29

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 00:00
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

54 of 4549

EAB) (1725)

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:34:29

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 22:42
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:34:29

Yes <input type="checkbox"/>	
PC Time stamp	18 AUG 2020 05:11
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3172038

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 15:04:50

Generated On: 09 Jun 2021 15:34:29

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 18 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3172038

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 15:04:50

Generated On: 09 Jun 2021 15:34:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172038

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 15:04:50

Generated On: 09 Jun 2021 15:34:29

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 26 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3172038

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 15:04:50

Generated On: 09 Jun 2021 15:34:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172038

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 15:04:50

Generated On: 09 Jun 2021 15:34:29

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments
UNABLE TO CONTACT
SUBJECT. LEFT MESSAGE TO
CALL SITE BACK.

If Contact Not Made, please provide Comments

US3172038

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 15:04:50

Generated On: 09 Jun 2021 15:34:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172038

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 15:04:50

Generated On: 09 Jun 2021 15:34:29

Was this visit performed? Yes ☐
No ☒

Visit date (dd MMM yyyy) _____

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

Folder OID VISIT2

US3172038

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Feb 2021 15:04:50

Generated On: 09 Jun 2021 15:34:29

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
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="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
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	

US3172038

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Feb 2021 15:04:50

Generated On: 09 Jun 2021 15:34:29

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	

US3172038

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 15:04:50

Generated On: 09 Jun 2021 15:34:29

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.

US3172038

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 15:04:50

Generated On: 09 Jun 2021 15:34:29

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 SAE

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? _____

US3172038

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 15:04:50

Generated On: 09 Jun 2021 15:34:29

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3172038

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Feb 2021 15:04:50

Generated On: 09 Jun 2021 15:34:29

Collection date (dd MMM yyyy)

Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	No		
Nasopharyngeal Swab 2	No		

US3172038

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 15:04:50

Generated On: 09 Jun 2021 15:34:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172038

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 15:04:50

Generated On: 09 Jun 2021 15:34:29

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 15 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3172038

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 15:04:50

Generated On: 09 Jun 2021 15:34:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172038

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 15:04:50

Generated On: 09 Jun 2021 15:34:29

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 24 SEP 2020

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

Comments
If Contact Not Made, please provide Comments
SUBJECT COULD NOT BE REACHED. CONTACTED EMERGENCY CONTACT AND THEY MENTIONED SUBJECT IS AGAIN HOSPITALIZED FOR THE SAME ISSUE (ACUTE PYELONEPHRITIS, NOT RESOLVED)

US3172038

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 15:04:50

Generated On: 09 Jun 2021 15:34:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172038

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 03 Mar 2021 13:49:04

Generated On: 09 Jun 2021 15:34:29

Was Contact Attempted? Yes ☐
No ☒

Date of Contact or Contact Attempt (dd MMM yyyy)

Please select one status for the follow-up contact

Contact Made ☐
Contact Not Made ☐

Comments NOT DONE

If Contact Not Made, please provide Comments

US3172038

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 15:04:50

Generated On: 09 Jun 2021 15:34:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172038

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 14:34:14

Generated On: 09 Jun 2021 15:34:29

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 VISIT3

US3172038

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 14:34:14

Generated On: 09 Jun 2021 15:34:29

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3172038

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 14:34:14

Generated On: 09 Jun 2021 15:34:29

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.

US3172038

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 14:34:14

Generated On: 09 Jun 2021 15:34:29

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3172038

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 15:04:50

Generated On: 09 Jun 2021 15:34:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172038

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	11 OCT 2020 00:22:18
Patient Cloud Open Date & Time	11 OCT 2020 00:01
Patient Cloud Close Date & Time	15 OCT 2020 23:59

US3172038

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 OCT 2020 22:44:10

Patient Cloud Open Date & Time

18 OCT 2020 00:01

Patient Cloud Close Date & Time

22 OCT 2020 23:59

US3172038

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 OCT 2020 05:56:32

Patient Cloud Open Date & Time

25 OCT 2020 00:01

Patient Cloud Close Date & Time

29 OCT 2020 23:59

US3172038

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 NOV 2020 13:45:06

Patient Cloud Open Date & Time

08 NOV 2020 00:01

Patient Cloud Close Date & Time

12 NOV 2020 23:59

US3172038

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

US3172038

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2020 00:01

Patient Cloud Close Date & Time

19 NOV 2020 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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 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"/>

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2020 00:01

Patient Cloud Close Date & Time

23 NOV 2020 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2020 00:01

Patient Cloud Close Date & Time

30 NOV 2020 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

05 DEC 2020 05:42:29

Patient Cloud Open Date & Time

03 DEC 2020 00:01

Patient Cloud Close Date & Time

07 DEC 2020 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 DEC 2020 07:47:42
Patient Cloud Open Date & Time	10 DEC 2020 00:01
Patient Cloud Close Date & Time	14 DEC 2020 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2020 00:01

Patient Cloud Close Date & Time

21 DEC 2020 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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 <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°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="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"/>

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

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

Date and time of submission

Patient Cloud Open Date & Time

24 DEC 2020 00:01

Patient Cloud Close Date & Time

28 DEC 2020 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

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

Date and time of submission

Patient Cloud Open Date & Time

31 DEC 2020 00:01

Patient Cloud Close Date & Time

04 JAN 2021 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Patient Cloud Close Date & Time

11 JAN 2021 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Patient Cloud Close Date & Time

18 JAN 2021 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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 <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"/>

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Patient Cloud Close Date & Time

25 JAN 2021 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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 <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°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="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"/>

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

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

Date and time of submission

Patient Cloud Open Date & Time

28 JAN 2021 00:01

Patient Cloud Close Date & Time

01 FEB 2021 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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"/>

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Patient Cloud Close Date & Time

08 FEB 2021 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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°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="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"/>

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Patient Cloud Close Date & Time

15 FEB 2021 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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°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"/>

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

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

Date and time of submission

Patient Cloud Open Date & Time

18 FEB 2021 00:01

Patient Cloud Close Date & Time

22 FEB 2021 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 MAR 2021 13:21:09

Patient Cloud Open Date & Time

25 FEB 2021 00:01

Patient Cloud Close Date & Time

01 MAR 2021 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 MAR 2021 03:18:51

Patient Cloud Open Date & Time

04 MAR 2021 00:01

Patient Cloud Close Date & Time

08 MAR 2021 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 MAR 2021 17:30:40

Patient Cloud Open Date & Time

11 MAR 2021 00:01

Patient Cloud Close Date & Time

15 MAR 2021 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 MAR 2021 06:00:26

Patient Cloud Open Date & Time

18 MAR 2021 00:01

Patient Cloud Close Date & Time

22 MAR 2021 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 MAR 2021 17:50:35

Patient Cloud Open Date & Time

25 MAR 2021 00:01

Patient Cloud Close Date & Time

29 MAR 2021 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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 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	01 APR 2021 04:29:25
Patient Cloud Open Date & Time	01 APR 2021 00:01
Patient Cloud Close Date & Time	05 APR 2021 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 APR 2021 05:20:01

Patient Cloud Open Date & Time

08 APR 2021 00:01

Patient Cloud Close Date & Time

12 APR 2021 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 APR 2021 07:25:12

Patient Cloud Open Date & Time

15 APR 2021 00:01

Patient Cloud Close Date & Time

19 APR 2021 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 APR 2021 00:02:21

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Date and time of submission

29 APR 2021 05:19:14

Patient Cloud Open Date & Time

29 APR 2021 00:01

Patient Cloud Close Date & Time

03 MAY 2021 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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°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"/>

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Patient Cloud Close Date & Time

10 MAY 2021 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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="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°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="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"/>

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

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

Date and time of submission

Patient Cloud Open Date & Time

13 MAY 2021 00:01

Patient Cloud Close Date & Time

17 MAY 2021 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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="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"/>

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

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

Date and time of submission

Patient Cloud Open Date & Time

20 MAY 2021 00:01

Patient Cloud Close Date & Time

24 MAY 2021 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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 <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"/>

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

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

Date and time of submission

Patient Cloud Open Date & Time

27 MAY 2021 00:01

Patient Cloud Close Date & Time

31 MAY 2021 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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"/>

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

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

Date and time of submission

Patient Cloud Open Date & Time

03 JUN 2021 00:01

Patient Cloud Close Date & Time

07 JUN 2021 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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 <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°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="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"/>

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Patient Cloud Close Date & Time

14 JUN 2021 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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 <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"/>

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Patient Cloud Close Date & Time

21 JUN 2021 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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°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="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"/>

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

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

Date and time of submission

Patient Cloud Open Date & Time

24 JUN 2021 00:01

Patient Cloud Close Date & Time

28 JUN 2021 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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 <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°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="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"/>

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Patient Cloud Close Date & Time

05 JUL 2021 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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°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="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"/>

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Patient Cloud Close Date & Time

12 JUL 2021 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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°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"/>

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Patient Cloud Close Date & Time

19 JUL 2021 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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="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°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="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"/>

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Patient Cloud Close Date & Time

26 JUL 2021 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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 <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"/>

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Patient Cloud Close Date & Time

02 AUG 2021 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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="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°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="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"/>

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Patient Cloud Close Date & Time

09 AUG 2021 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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 <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°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="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"/>

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

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

Date and time of submission

Patient Cloud Open Date & Time

12 AUG 2021 00:01

Patient Cloud Close Date & Time

16 AUG 2021 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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 <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"/>

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Patient Cloud Close Date & Time

23 AUG 2021 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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°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"/>

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Patient Cloud Close Date & Time

30 AUG 2021 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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 <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"/>

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Patient Cloud Close Date & Time

06 SEP 2021 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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 <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"/>

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Patient Cloud Close Date & Time

13 SEP 2021 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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="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"/>

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Patient Cloud Close Date & Time

20 SEP 2021 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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°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"/>

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Patient Cloud Close Date & Time

27 SEP 2021 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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°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"/>

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Patient Cloud Close Date & Time

04 OCT 2021 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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°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="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"/>

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Patient Cloud Close Date & Time

11 OCT 2021 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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="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°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="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"/>

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Patient Cloud Close Date & Time

18 OCT 2021 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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="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°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="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"/>

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Patient Cloud Close Date & Time

25 OCT 2021 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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°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"/>

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

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

Date and time of submission

Patient Cloud Open Date & Time

28 OCT 2021 00:01

Patient Cloud Close Date & Time

01 NOV 2021 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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 <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"/>

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Patient Cloud Close Date & Time

08 NOV 2021 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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°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"/>

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Patient Cloud Close Date & Time

15 NOV 2021 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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="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°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="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"/>

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

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

Date and time of submission

Patient Cloud Open Date & Time

18 NOV 2021 00:01

Patient Cloud Close Date & Time

22 NOV 2021 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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="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°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="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"/>

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Patient Cloud Close Date & Time

29 NOV 2021 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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 <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"/>

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Patient Cloud Close Date & Time

06 DEC 2021 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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 <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"/>

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Patient Cloud Close Date & Time

13 DEC 2021 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Patient Cloud Close Date & Time

20 DEC 2021 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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°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="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"/>

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Patient Cloud Close Date & Time

27 DEC 2021 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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 <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°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="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"/>

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Patient Cloud Close Date & Time

03 JAN 2022 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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="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°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="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"/>

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Patient Cloud Close Date & Time

10 JAN 2022 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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 <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"/>

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

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

Date and time of submission

Patient Cloud Open Date & Time

13 JAN 2022 00:01

Patient Cloud Close Date & Time

17 JAN 2022 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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°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="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"/>

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

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

Date and time of submission

Patient Cloud Open Date & Time

20 JAN 2022 00:01

Patient Cloud Close Date & Time

24 JAN 2022 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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 <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°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="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"/>

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

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

Date and time of submission

Patient Cloud Open Date & Time

27 JAN 2022 00:01

Patient Cloud Close Date & Time

31 JAN 2022 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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="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"/>

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

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

Date and time of submission

Patient Cloud Open Date & Time

03 FEB 2022 00:01

Patient Cloud Close Date & Time

07 FEB 2022 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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="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°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="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"/>

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Patient Cloud Close Date & Time

14 FEB 2022 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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 <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°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="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"/>

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Patient Cloud Close Date & Time

21 FEB 2022 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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 <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°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="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"/>

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

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

Date and time of submission

Patient Cloud Open Date & Time

24 FEB 2022 00:01

Patient Cloud Close Date & Time

28 FEB 2022 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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 <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°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="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"/>

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

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

Date and time of submission

Patient Cloud Open Date & Time

03 MAR 2022 00:01

Patient Cloud Close Date & Time

07 MAR 2022 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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 <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"/>

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Patient Cloud Close Date & Time

14 MAR 2022 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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 <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°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="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"/>

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Patient Cloud Close Date & Time

21 MAR 2022 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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 <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"/>

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

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

Date and time of submission

Patient Cloud Open Date & Time

24 MAR 2022 00:01

Patient Cloud Close Date & Time

28 MAR 2022 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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="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°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="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"/>

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

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

Date and time of submission

Patient Cloud Open Date & Time

31 MAR 2022 00:01

Patient Cloud Close Date & Time

04 APR 2022 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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="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°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="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"/>

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Patient Cloud Close Date & Time

11 APR 2022 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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"/>

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Patient Cloud Close Date & Time

18 APR 2022 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Patient Cloud Close Date & Time

25 APR 2022 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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="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°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="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"/>

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

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

Date and time of submission

Patient Cloud Open Date & Time

28 APR 2022 00:01

Patient Cloud Close Date & Time

02 MAY 2022 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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 <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°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="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"/>

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Patient Cloud Close Date & Time

09 MAY 2022 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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°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"/>

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

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

Date and time of submission

Patient Cloud Open Date & Time

12 MAY 2022 00:01

Patient Cloud Close Date & Time

16 MAY 2022 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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°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"/>

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Patient Cloud Close Date & Time

23 MAY 2022 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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="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°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="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"/>

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Patient Cloud Close Date & Time

30 MAY 2022 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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 <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"/>

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Patient Cloud Close Date & Time

06 JUN 2022 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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="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°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="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"/>

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Patient Cloud Close Date & Time

13 JUN 2022 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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 <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°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="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"/>

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Patient Cloud Close Date & Time

20 JUN 2022 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Patient Cloud Close Date & Time

27 JUN 2022 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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="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°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="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"/>

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Patient Cloud Close Date & Time

04 JUL 2022 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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="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"/>

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Patient Cloud Close Date & Time

11 JUL 2022 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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="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°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="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"/>

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Patient Cloud Close Date & Time

18 JUL 2022 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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="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°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="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"/>

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Patient Cloud Close Date & Time

25 JUL 2022 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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 <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"/>

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

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

Date and time of submission

Patient Cloud Open Date & Time

28 JUL 2022 00:01

Patient Cloud Close Date & Time

01 AUG 2022 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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 <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"/>

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Patient Cloud Close Date & Time

08 AUG 2022 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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 <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"/>

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Patient Cloud Close Date & Time

15 AUG 2022 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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="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"/>

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

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

Date and time of submission

Patient Cloud Open Date & Time

18 AUG 2022 00:01

Patient Cloud Close Date & Time

22 AUG 2022 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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 <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"/>

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Patient Cloud Close Date & Time

29 AUG 2022 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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="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°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="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"/>

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Patient Cloud Close Date & Time

05 SEP 2022 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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°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"/>

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Patient Cloud Close Date & Time

12 SEP 2022 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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="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°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="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"/>

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Patient Cloud Close Date & Time

19 SEP 2022 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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 <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"/>

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Patient Cloud Close Date & Time

26 SEP 2022 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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 <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°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="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"/>

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Patient Cloud Close Date & Time

03 OCT 2022 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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°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"/>

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Patient Cloud Close Date & Time

10 OCT 2022 23:59

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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="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"/>

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

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

Date and time of submission

Patient Cloud Open Date & Time

13 OCT 2022 00:01

Patient Cloud Close Date & Time

17 OCT 2022 23:59

US3172038

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:34:29

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
Yes	No	01 MAR 2021 13:21:30

US3172038

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 03 Mar 2021 13:49:04

Generated On: 09 Jun 2021 15:34:29

Was Contact Attempted? Yes ☐
No ☒

Date of Contact or Contact Attempt (dd MMM yyyy)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

MISSED

If Contact Not Made, please provide Comments

US3172038

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 15:04:50

Generated On: 09 Jun 2021 15:34:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172038

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 03 Mar 2021 13:49:04

Generated On: 09 Jun 2021 15:34:29

Was Contact Attempted? Yes ☐
No ☒

Date of Contact or Contact Attempt (dd MMM yyyy)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

MISSED

If Contact Not Made, please provide Comments

US3172038

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 15:04:50

Generated On: 09 Jun 2021 15:34:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172038

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 03 Mar 2021 13:49:04

Generated On: 09 Jun 2021 15:34:29

Was Contact Attempted? Yes ☐
No ☒

Date of Contact or Contact Attempt (dd MMM yyyy)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

MISSED

If Contact Not Made, please provide Comments

US3172038

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 15:04:50

Generated On: 09 Jun 2021 15:34:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172038

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 15:04:50

Generated On: 09 Jun 2021 15:34:29

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 05 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3172038

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 15:04:50

Generated On: 09 Jun 2021 15:34:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172038

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 22 Apr 2021 15:56:30

Generated On: 09 Jun 2021 15:34:29

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 VISIT4

US3172038

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 22 Apr 2021 15:56:30

Generated On: 09 Jun 2021 15:34:29

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3172038

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Apr 2021 15:56:30

Generated On: 09 Jun 2021 15:34:29

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.

US3172038

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Apr 2021 15:56:30

Generated On: 09 Jun 2021 15:34:29

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3172038

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 22 Apr 2021 15:56:30

Generated On: 09 Jun 2021 15:34:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172038

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 22 Apr 2021 15:56:30

Generated On: 09 Jun 2021 15:34:29

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3172038

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 22 Apr 2021 15:56:30

Generated On: 09 Jun 2021 15:34:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172038

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:29

Was Contact Attempted? Yes ☐
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3172038

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:29

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3172038

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:34:29

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"/>

US3172038

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 15:34:29

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3172038

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

Form: Visit Date

Data signed: (b) (4) 22 Apr 2021 15:56:30

Generated On: 09 Jun 2021 15:34:29

Was this visit performed? Yes ☒
No ☐

Visit date (dd MMM yyyy) 12 MAR 2021

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

Folder OID UNBLND_DECIDE

US3172038

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

Form: Unblinding

Data signed: (b) (4) 22 Apr 2021 15:56:30

Generated On: 09 Jun 2021 15:34:29

Date of updated informed consent (dd MMM yyyy)	06 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (dd MMM yyyy)	12 MAR 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	

US3172038

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Apr 2021 15:56:30

Generated On: 09 Jun 2021 15:34:29

Was the sample collected? Yes ☒
No ☐

Collection date (dd MMM yyyy) 12 MAR 2021

Collection time (00:00-23:59) 13:30 (24 HR)

Collection date and time (derived) 12 MAR 2021 13:30

US3172038

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 22 Apr 2021 15:56:30

Generated On: 09 Jun 2021 15:34:29

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

Collection date (dd MMM yyyy)	12 MAR 2021
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Collection time (00:00 - 23:59)	13:31
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Collection Date and Time (derived)	12 MAR 2021 13:31
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US3172038

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 16 Feb 2021 15:04:48

Generated On: 09 Jun 2021 15:34:29

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3172038

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:29

AEID

Adverse event

RIGHT KIDNEY
NEPHROLITHIASIS

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)

29 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒

No ☐

If not Ongoing, end date (dd MMM yyyy)

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)

US3172038

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:29

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	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input 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)	_____

US3172038

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:29

AEID	USA-US118-2020-MRNA-1273-P30 1000001
Adverse event	ACUTE PYELONEPHRITIS (RIGHT KIDNEY)
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	01 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	26 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	True
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	01 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	04 SEP 2020
Admitted to ICU?	Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	3
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Folder: Adverse Events

Form: Adverse Events (2)

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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input checked="" type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
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	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:29

SUBJECT EMERGENCY
CONTACT REPORTED THAT
THE PATIENT WAS
HOSPITALIZED ON SAME DATE
31AUG2020 IN ICU WITH ACUTE
EXACERBATION OF
NEPHROLITHIASIS AND THAT
SYMPTOMS WERE GETTING
WORSE. SUBJECT WAS
TRANSFERED TO HOSPITAL
VIA RESCUE. RECORDS WILL
BE REQUESTED AS SOON AS
PATIENT IS DISCHARGED.
09SEP2020- DISCHARGED
RECORDS RECEIVED BY EMAIL
FROM SUBJECT. SHE HAS
PYELONEPHRITIS CONFIRMED
BY NEPHROSTOGRAM
ANTEGRADE UROGRAPHY ON
01SEP2020 (AT ADMISSION).
THIS EVENT LEAD TO A SEPTIC
SHOCK, ELEVATED
TROPINONINS AND SEPTIC
ACIDOSIS BEGINNING ICU
ADMISSION FOR IV ABS, IV
FLUIDS, AND PERCUTANEOUS
NEPHROSTAMY TUBE FOR
RIGHT KIDNEY STONE/ RIGHT
URETER DECOMPRESSION. STILL
WAITING FOR RECORDS FROM
HOSPITAL FOR DETAILS.
RECOVERING AT HOME WITH
NURSING CARE TO COMPLETE
ABS IV TREATMENT AND
DRAINAGE/ WOUND CARE
WILL FOLLOW UP. DISCUSSED
WITH PI WILL DISCHARGE IP

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:29

TREATMENT. INITIAL SIGNS
AND SYMPTOMS: RIGHT UPPER
QUADRANT ABDOMEN PAIN,
TACHYCARDIA, FEVER,
HYPOSTENSION, DIAPHORESIS,
TRACHYPNEA, ANXIETY.
ADMISSION
31AUG2020-DISCHARGED
04SEP2020 SUBJECT ADMITTED
DUE TO RECURRENT R FLANK
PAIN AND FEVER FOR 2 DAYS
BEFORE ADMISSION. SHE WAS
FOUND TO HAVE UROSEPSIS
WITH E. COLI BACTERIA FROM
PYELOREPHITIS WITH
OBSTRUCTING R PROXIMAL
URETERAL STONE AND HIGH R
RENAL STONE BURDEN WITH
SECONDARY
HYDRONEPHOROSIS. CHEST
X-RAY DONE ON 01SEP2020
WITH ASYMPTOMATIC
ELEVATION OF R
HEMIDIAPHRAGM. CT CHEST,
ABDOMINAL PELVIS WITH
CONTRAST CONFIRMED THE R
PYELOPHRITIS FINDINGS AND
THE OBSTRUCTION RENAL
CALCULUS AT R PROXIMAL
UTERUS CRUISING
HYDRONEPHROSIS. CT BRAIN
WITHOUT CONTRAST
01SEP2020 WITHOUT ACUTE
FINDINGS. SUBJECT WAS
DISCHARGED HOME ON
04SEP20 ON A STABLE
CONDITION WITH PO DOUBLE

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:29

STRENGTH BACTRIN BID TO
COMPLETE 14 DAYS OF ABS
COURSE 01SEP-18SEP SHE LEFT
THE HOSPITAL WITH A
NEPHROSTOMY TUBE AND
UROLOGIST FOLLOW UP TO
SCHEDULE A URETHOSCOPY
FOR REMOVAL OF RENAL
STONES. UNABLE TO
COMPLETE NARRATIVE DUE
TO NOT ENOUGH SPACE.

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

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:34:29

AEID	USA-US118-2020-MRNA-1273-P30 1000001
Adverse event	SEPTIC SHOCK
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	1 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	3 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	True
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	1 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	4 SEP 2020
Admitted to ICU?	Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	3

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:34:29

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	True
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	SEPTIC SHOCK, SECONDARY TO AN ACUTE PYELONEPHRITIS REQUIRING ICU ADMISSION, IV FLUIDS, IV ABS PERCUTANEOUS DRAINAGE AND OTHER ACUTE MEASURES. PENDING MEDICAL RECORDS TO COMPLETE INFO.DISCUSSED WITH PI WILL DISCHARGE IP TREATMENT.

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Folder: Adverse Events

Form: Adverse Events (3)

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

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:34:29

AEID

Adverse event

UPDATE FOR ORIGINAL SAE.
SECOND HOSPITALIZATION
DUE TO UNRESOLVED RIGHT
KIDNEY PYELONEPHRITIS

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) 22 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy) 26 SEP 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 ☐

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Folder: Adverse Events

Form: Adverse Events (4)

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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 <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	True
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)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:34:29

AEID

Adverse event

ACUTE RENAL COLIC

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)

29 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

30 AUG 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☐

Grade 3/Severe ☒

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

Persistent or significant disability or incapacity

False

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:34:29

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 type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:34:29

AEID	USA-US118-2020-MRNA-1273-P30 1000001
Adverse event	ACUTE HYPOXEMIC RESPIRATOY FAILURE
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	1 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	3 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	True
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	1 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	4 SEP 2020
Admitted to ICU?	Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	3
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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:34:29

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	True
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	INTUBATED IN ICU ON 01SEP2020-EXTUBATED
Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	1

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:34:29

AEID	USA-US118-2020-MRNA-1273-P30 1000001
Adverse event	PROFOUND METABOLIC ACIDOSIS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	1 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	3 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	True
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	1 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	4 SEP 2020
Admitted to ICU?	Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	3
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Folder: Adverse Events

Form: Adverse Events (7)

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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	True
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	PROFOUND METABOLIC ACIDOSIS SECONDARY TO SEPTIC SHOCK, SEVER SEPSIS, REQUIRING INTUBATION-EXUBATED ON THE NEXT DAY 02SEP2020.
Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	1
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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 16 Feb 2021 15:04:49

Generated On: 09 Jun 2021 15:34:29

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:34:29

Name of Medication	ZOFRAN
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	VOMITING
Dose per administration	4
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify	
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input checked="" type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:34:29

	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 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		31 AUG 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		3
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:34:29

Name of Medication	ADENOSINE 6MG X2 VIALS
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	TACHYCHARDIA
Dose per administration	12
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input checked="" type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:34:29

	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 checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
<hr/>		
If route of administration is Other, specify <hr/>		
Start date (<i>dd MMM yyyy</i>)		01 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
If not Ongoing, End date (<i>dd MMM yyyy</i>)		01 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
Separate Dosage Number (derived)		<hr/>
Interval Dosage Unit Number (derived)		<hr/>
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:34:29

Name of Medication	AMIODARONE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>

Indication	TACHYCHARDIA
------------	--------------

Dose per administration	150
-------------------------	-----

Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
-----------	--

If dose unit is Other, specify

Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input checked="" type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
-----------	--

If frequency is Other, specify

Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>
-------------------------	--

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:34:29

	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 checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
<hr/>		
If route of administration is Other, specify <hr/>		
Start date (<i>dd MMM yyyy</i>)		01 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
If not Ongoing, End date (<i>dd MMM yyyy</i>)		01 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
Separate Dosage Number (derived)		<hr/>
Interval Dosage Unit Number (derived)		<hr/>
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:34:29

Name of Medication	VANCOMYCIN
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	PNEUMONEPHRITIS/SEPTIC SHOCK
Dose per administration	2
Dose unit	mg <input type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input checked="" type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input checked="" type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify _____	
Route of administration	Oral <input type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:34:29

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		01 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:34:29

Name of Medication	CEFEPIME 1 GRAM EACH
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	PYELONEPHRITIS/SEPTIC SHOCK
Dose per administration	2
Dose unit	mg <input type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input checked="" type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify _____	
Route of administration	Oral <input type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:34:29

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
<hr/>		
If route of administration is Other, specify		
Start date (dd MMM yyyy)	01 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
<hr/>		
If not Ongoing, End date (dd MMM yyyy)		02 SEP 2020
Was this medication taken for solicited event?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
<hr/>		
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="radio"/>	
	803 <input type="radio"/>	
	804 <input checked="" type="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:34:29

Name of Medication	CEFTRIAXONE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	PYELONEPHRITIS
Dose per administration	1
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input checked="" type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input checked="" type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:34:29

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 checked="" 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)	03 SEP 2020
Start date completely unknown	False
Ongoing?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	04 SEP 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:34:29

Name of Medication BACTRIN
(TRINETHOPRIM/SULFAMETHO
XAZOLE)

Prophylaxis Yes ☐
No ☒

Indication PYELONEPHRITIS

Dose per administration 800/160

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:34:29

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	04 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	18 SEP 2020	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input checked="" type="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:34:29

Name of Medication	TYLENOL
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	FEVER
Dose per administration	325
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input checked="" type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:34:29

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input checked="" type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
<hr/>		
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy)		01 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:34:29

Name of Medication	FAMOTIDINE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	VOMITING/NAUSEA
Dose per administration	1
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input checked="" type="radio"/>
If dose unit is Other, specify	VIAL 20MG/2ML
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:34:29

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 checked="" 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)	01 SEP 2020
Start date completely unknown	False
Ongoing?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	03 SEP 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:34:29

Name of Medication	FENTANYL
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	RIGHT UPPER QUADRANT PAIN ABDOMEN
Dose per administration	1
Dose unit	mg <input type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input checked="" type="checkbox"/>
If dose unit is Other, specify	VIAL 25MCG/0.5ML
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input checked="" type="checkbox"/>
If frequency is Other, specify	EVERY 2 HOURS/ AS NEEDED
Route of administration	Oral <input type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:34:29

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
<hr/>		
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy)		02 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
<hr/>		
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:34:29

Name of Medication	LACTATED RINGER
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	METABOLIC ACIDOSIS
Dose per administration	1000
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input checked="" type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input checked="" type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:34:29

	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 checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
<hr/>		
If route of administration is Other, specify <hr/>		
Start date (dd MMM yyyy)		01 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy)		01 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
Separate Dosage Number (derived)		<hr/>
Interval Dosage Unit Number (derived)		<hr/>
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:34:29

Name of Medication	NOREPINEPHRINE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	ANESTHESIA FOR RESPIRATORY TUBE PLACEMENT
Dose per administration	4
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input checked="" type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:34:29

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" 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)	01 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		01 SEP 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:34:29

Name of Medication	PROPOFOL
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	ANESTHESIA FOR RESPIRATORY TUBE PLACEMENT
Dose per administration	1000
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input checked="" type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:34:29

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)		01 SEP 2020
Was this medication taken for solicited event?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:34:29

Name of Medication	VASOPRESSIN
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	TACHYCARDIA/HYPOTENSION
Dose per administration	50
Dose unit	mg <input type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input checked="" type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify	
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input checked="" type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify	
Route of administration	Oral <input type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/>

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:34:29

	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 checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
<hr/>		
If route of administration is Other, specify <hr/>		
Start date (<i>dd MMM yyyy</i>)		01 SEP 2020
Start date completely unknown		False
Ongoing?	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
<hr/>		
If not Ongoing, End date (<i>dd MMM yyyy</i>)		01 SEP 2020
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
<hr/>		
Separate Dosage Number (derived)	<hr/>	
Interval Dosage Unit Number (derived)	<hr/>	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:34:29

Name of Medication	POTASSIUM CHLORIDE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	METABOLIC ACIDOSIS
Dose per administration	1
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input checked="" type="radio"/>
If dose unit is Other, specify	40 MEQ/100 ML
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input checked="" type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:34:29

	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 checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
<hr/>		
If route of administration is Other, specify <hr/>		
Start date (dd MMM yyyy)		01 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy)		01 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
Separate Dosage Number (derived)		<hr/>
Interval Dosage Unit Number (derived)		<hr/>
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:34:29

Name of Medication	SODIUM BICARBONATE 8.4%
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	METABOLIC ACIDOSIS
Dose per administration	100/50
Dose unit	mg <input type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input checked="" type="checkbox"/>
If dose unit is Other, specify	MEQ/ML
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input checked="" type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify	
Route of administration	Oral <input type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:34:29

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 checked="" 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)	01 SEP 2020
Start date completely unknown	False
Ongoing?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 01 SEP 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"/>

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:34:29

Name of Medication	SODIUM CHLORIDE 0.9%
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	HYDRATION (OPEN LINE FOR MEDICATION ADMINISTRATION)
Dose per administration	1000
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input checked="" type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:34:29

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	02 SEP 2020	
Was this medication taken for solicited event?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="radio"/>	
	803 <input type="radio"/>	
	804 <input checked="" type="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:34:29

Name of Medication	TORADOL
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	RIGHT UPPER QUADRANT ABDOMEN PAIN
Dose per administration	30
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify	
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input checked="" type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify	
Route of administration	Oral <input type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/>

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:34:29

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy) 01 SEP 2020		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:34:29

Name of Medication	TYLENOL
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	FEVER
Dose per administration	650
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input checked="" type="radio"/>
If frequency is Other, specify	
Route of administration	EVERY 6 HOURS/ AS NEEDED Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:34:29

	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"/>
<hr/>		
If route of administration is Other, specify <input type="text"/>		
<hr/>		
Start date (dd MMM yyyy)		01 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy)		01 SEP 2020
<hr/>		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
Separate Dosage Number (derived)		<input type="text"/>
Interval Dosage Unit Number (derived)		<input type="text"/>
Interval Dosage Definition (derived)		802 <input type="checkbox"/>
		803 <input type="checkbox"/>
		804 <input type="checkbox"/>

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:34:29

Name of Medication	LEVOFLOXACIN
Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>
Indication	PROPHYLAXIS AFTER REMOVED STEM RIGHT URETER
Dose per administration	500
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:34:29

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	06 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3172038

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 16 Feb 2021 15:04:49

Generated On: 09 Jun 2021 15:34:29

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3172038

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 09 Jun 2021 15:34:29

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
01 SEP 2020	CHEST X-RAY	Adverse Event	
01 SEP 2020	CT CHEST, ABDOMEN/PELVIS	Adverse Event	
01 SEP 2020	CT BRAIN	Adverse Event	
01 SEP 2020	RIGHT URETRAL STENT PLACEMENT	Adverse Event	
01 SEP 2020	INTUBATED	Adverse Event	
01 SEP 2020	NEPHROSTOGRAM ANTEGRADE UROGRAPHY.	Adverse Event	
01 SEP 2020	PERCUTANEOUS NEPHROSTOMY TUBE	Adverse Event	
01 SEP 2020	SECONDARY HYDRONEPHROSIS	Adverse Event	
01 SEP 2020	SCHEDULE A URETHOSCOPY	Adverse Event	
01 SEP 2020	PERCUTANEOUS NEPHROSTOMY	Adverse Event	
06 APR 2021	REMOVED ARTERY DECOMPRESSION DEVICE RIGHT URETER	Adverse Event	

US3172038

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 16 Feb 2021 15:04:49

Generated On: 09 Jun 2021 15:34:29

Date of dosing discontinuation (dd MMM yyyy) 4 SEP 2020

Primary reason for dosing discontinuation

AE (specify)	<input type="checkbox"/>
SAE (specify)	<input checked="" 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 type="checkbox"/>
Other	<input type="checkbox"/>

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify SAE #2

US3172038

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 16 Feb 2021 15:04:49

Generated On: 09 Jun 2021 15:34:29

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 ☐

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Data signed: (b) (4) 23 Feb 2021 14:34:14

Generated On: 09 Jun 2021 15:34:29

SAEID	USA-US118-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	13

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Data signed: (b) (4) 23 Feb 2021 14:34:14

Generated On: 09 Jun 2021 15:34:29

SAEID	USA-US118-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	13
Date of submission (Pre-filled from custom function)	02/SEP/2020 20:02
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

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Data signed: (b) (4) 23 Feb 2021 14:34:14

Generated On: 09 Jun 2021 15:34:29

SAEID	USA-US118-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	13
Date of submission (Pre-filled from custom function)	10/SEP/2020 20:12
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

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Data signed: (b) (4) 23 Feb 2021 14:34:14

Generated On: 09 Jun 2021 15:34:29

SAEID	USA-US118-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	13
Date of submission (Pre-filled from custom function)	25/SEP/2020 14:14
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

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Data signed: (b) (4) 23 Feb 2021 14:34:14

Generated On: 09 Jun 2021 15:34:29

SAEID	USA-US118-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	13
Date of submission (Pre-filled from custom function)	05/OCT/2020 10:09
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

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Data signed: (b) (4) 23 Feb 2021 14:34:14

Generated On: 09 Jun 2021 15:34:29

SAEID	USA-US118-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	13
Date of submission (Pre-filled from custom function)	22/OCT/2020 19:17
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

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Data signed: (b) (4) 23 Feb 2021 14:34:14

Generated On: 09 Jun 2021 15:34:29

SAEID	USA-US118-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	13
Date of submission (Pre-filled from custom function)	22/OCT/2020 21:38
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

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form (7)

Data signed: (b) (4) 23 Feb 2021 14:34:14

Generated On: 09 Jun 2021 15:34:29

SAEID	USA-US118-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	13
Date of submission (Pre-filled from custom function)	28/OCT/2020 09:25
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form (8)

Data signed: (b) (4) 23 Feb 2021 14:34:14

Generated On: 09 Jun 2021 15:34:29

SAEID	USA-US118-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	13
Date of submission (Pre-filled from custom function)	09/NOV/2020 15:53
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

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form (9)

Data signed: (b) (4) 23 Feb 2021 14:34:14

Generated On: 09 Jun 2021 15:34:29

SAEID	USA-US118-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	13
Date of submission (Pre-filled from custom function)	12/NOV/2020 21:29
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

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form (10)

Data signed: (b) (4) 23 Feb 2021 14:34:14

Generated On: 09 Jun 2021 15:34:29

SAEID	USA-US118-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	13
Date of submission (Pre-filled from custom function)	20/NOV/2020 10:59
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

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form (11)

Data signed: (b) (4) 23 Feb 2021 14:34:14

Generated On: 09 Jun 2021 15:34:29

SAEID	USA-US118-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	13
Date of submission (Pre-filled from custom function)	20/NOV/2020 12:24
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

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form (12)

Data signed: (b) (4) 23 Feb 2021 14:34:14

Generated On: 09 Jun 2021 15:34:29

SAEID	USA-US118-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	13
Date of submission (Pre-filled from custom function)	01/FEB/2021 15:23
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form (13)

Data signed: (b) (4) 23 Feb 2021 14:34:14

Generated On: 09 Jun 2021 15:34:29

SAEID	USA-US118-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	13
Date of submission (Pre-filled from custom function)	19/FEB/2021 14:40
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

Audit

US3172038 (Prod: Suncoast Research Group LLC - ERN-PPDS)

US3172038

Form: Participant Creation

Generated On: 09 Jun 2021 15:34:29

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered 'US3172038'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	11 Aug 2020 14:54:49

US3172038

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:34:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:05:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 16:51:03

US3172038

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:05:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered '11 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	11 Aug 2020 14:54:49

US3172038

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:34:29

[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 08:05:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered 'Clinic (Clinic)'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 16:51:03

US3172038

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:34:29

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:05:51
User entered 'SCRN'	System	11 Aug 2020 16:51:03

US3172038

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered (b) (6) 1986'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	11 Aug 2020 14:54:50

US3172038

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:34:29

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:51
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
User entered '34'	Mariete Rendon (b) (4)	11 Aug 2020 16:51:52
	(b) (4)	

US3172038

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:34:29

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:51
User entered 'YEARS'	System	11 Aug 2020 16:51:52

US3172038

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:34:29

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:51
User entered '34'	System	11 Aug 2020 16:11:11

US3172038

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:34:29

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:51
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
User entered 'Female (F)'	Mariete Rendon (b) (4)	11 Aug 2020 16:51:52
	(b) (4)	

US3172038

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:34:29

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:51
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Mariete Rendon (b) (4)	11 Aug 2020 16:51:52
	(b) (4)	

US3172038

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:34:29

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:51
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
User entered 'I'	Mariete Rendon (b) (4)	11 Aug 2020 16:51:52
	(b) (4)	

US3172038

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:34:29

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered '0'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 16:51:52

US3172038

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:34:29

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:51
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	11 Aug 2020 16:51:52
	(b) (4)	

US3172038

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:34:29

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:51
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	11 Aug 2020 16:51:52
	(b) (4)	

US3172038

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:34:29

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:51
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	11 Aug 2020 16:51:52
	(b) (4)	

US3172038

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:34:29

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:51
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	11 Aug 2020 16:51:52
	(b) (4)	

US3172038

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:34:29

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:51
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	11 Aug 2020 16:51:52
	(b) (4)	

US3172038

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:34:29

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered '0'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 16:51:52

US3172038

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:34:29

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:51
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	11 Aug 2020 16:51:52
	(b) (4)	

US3172038

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:34:29

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:51
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
User entered '11 Aug 2020'	Mariete Rendon (b) (4)	11 Aug 2020 16:11:11
	(b) (4)	

US3172038

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:51
User entered 'Aug 2020'	System	11 Aug 2020 16:11:11

US3172038

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:51
User entered '2020'	System	11 Aug 2020 16:11:11

US3172038

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:34:29

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:51
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
User entered 'Amendment 1 (1)'	Mariete Rendon (b) (4)	11 Aug 2020 16:11:11
	(b) (4)	

US3172038

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:51
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
User entered 'Yes (Y)'	Mariete Rendon (b) (4)	11 Aug 2020 16:11:11
	(b) (4)	

US3172038

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:34:29

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:51
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	11 Aug 2020 16:11:11
	(b) (4)	

US3172038

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:34:29

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:51
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	11 Aug 2020 16:11:11
	(b) (4)	

US3172038

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:34:29

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:51
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
User entered 'No (N)'	Mariete Rendon (b) (4)	11 Aug 2020 16:11:11
	(b) (4)	

US3172038

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:34:29

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	11 Aug 2020 14:54:49

US3172038

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:34:29

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:51
User entered 'I'	System	11 Aug 2020 16:11:22

US3172038

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:05:51
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
User entered 'Yes (Y)'	Mariete Rendon (b) (4)	11 Aug 2020 16:11:22
	(b) (4)	

US3172038

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:34:29

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:05:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 16:53:10

US3172038

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:34:29

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:05:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 16:55:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 16:55:38
Data point term sent to Coder	System	11 Aug 2020 16:54:13
User entered 'Obese'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 16:53:25

US3172038

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:05:51
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
User entered 'UN UNK 2018'	Mariete Rendon (b) (4)	11 Aug 2020 16:53:25
	(b) (4)	

US3172038

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:34:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:05:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered '0'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 16:53:25

US3172038

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:34:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:05:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 16:53:25

US3172038

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:05:51
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	11 Aug 2020 16:53:25
	(b) (4)	

US3172038

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:34:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:05:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered '0'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 16:53:25

US3172038

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:05:51
User entered 'Jan 2018'	System	11 Aug 2020 16:53:25

US3172038

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:05:51
User entered '2018'	System	11 Aug 2020 16:53:25

US3172038

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:05:51
User entered empty.	System	11 Aug 2020 16:53:25

US3172038

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:05:51
User entered empty.	System	11 Aug 2020 16:53:25

US3172038

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:34:29

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:05:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Contraceptive methods female, PT: Female sterilisation, LLT: Tubal ligation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 16:55:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 16:55:18
Data point term sent to Coder	System	11 Aug 2020 16:54:20
User entered 'Tubal Ligation'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 16:54:06

US3172038

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:05:51
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
User entered 'UN UNK 2012'	Mariete Rendon (b) (4)	11 Aug 2020 16:54:06
	(b) (4)	

US3172038

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:34:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:05:51
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	11 Aug 2020 16:54:06
	(b) (4)	

US3172038

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:34:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:05:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 16:54:06

US3172038

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:05:51
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
User entered 'UN UNK 2012'	Mariete Rendon (b) (4)	11 Aug 2020 16:54:06
	(b) (4)	

US3172038

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:34:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:05:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered '0'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 16:54:06

US3172038

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:05:51
User entered 'Jan 2012'	System	11 Aug 2020 16:54:06

US3172038

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:05:51
User entered '2012'	System	11 Aug 2020 16:54:06

US3172038

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:05:51
User entered 'Jan 2012'	System	11 Aug 2020 16:54:06

US3172038

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:05:51
User entered '2012'	System	11 Aug 2020 16:54:06

US3172038

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:34:29

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:05:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User coded data point as SOC: Surgical and medical procedures, HLGT: Breast therapeutic procedures, HLT: Breast therapeutic procedures NEC, PT: Mammoplasty, LLT: Augmentation mammoplasty - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 16:56:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 16:56:10
Data point term sent to Coder	System	11 Aug 2020 16:55:21
User entered 'Breast Augmentation'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 16:54:28

US3172038

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:05:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered 'UN UNK 2009'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 16:54:28

US3172038

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:34:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:05:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered '0'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 16:54:28

US3172038

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:34:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:05:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 16:54:28

US3172038

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:05:51
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
User entered 'UN UNK 2009'	Mariete Rendon (b) (4)	11 Aug 2020 16:54:28
	(b) (4)	

US3172038

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:34:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:05:51
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	11 Aug 2020 16:54:28
	(b) (4)	

US3172038

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:05:51
User entered 'Jan 2009'	System	11 Aug 2020 16:54:28

US3172038

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:05:51
User entered '2009'	System	11 Aug 2020 16:54:28

US3172038

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:05:51
User entered 'Jan 2009'	System	11 Aug 2020 16:54:28

US3172038

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:05:51
User entered '2009'	System	11 Aug 2020 16:54:28

US3172038

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:34:29

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:05:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User coded data point as SOC: Surgical and medical procedures, HLGT: Breast therapeutic procedures, HLT: Breast therapeutic procedures NEC, PT: Mammoplasty, LLT: Augmentation mammoplasty - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 16:56:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 16:56:38
Data point term sent to Coder	System	11 Aug 2020 16:55:22
User entered 'Breast Augmentation'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 16:54:52

US3172038

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:05:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered 'UN UNK 2017'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 16:54:52

US3172038

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:34:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:05:51
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	11 Aug 2020 16:54:52
	(b) (4)	

US3172038

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:34:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:05:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 16:54:52

US3172038

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:05:51
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
User entered 'UN UNK 2017'	Mariete Rendon (b) (4)	11 Aug 2020 16:54:52
	(b) (4)	

US3172038

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:34:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:05:51
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	11 Aug 2020 16:54:52
	(b) (4)	

US3172038

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:34:29

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:05:51
User entered 'Jan 2017'	System	11 Aug 2020 16:54:52

US3172038

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:05:51
User entered '2017'	System	11 Aug 2020 16:54:52

US3172038

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:05:51
User entered 'Jan 2017'	System	11 Aug 2020 16:54:52

US3172038

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:05:51
User entered '2017'	System	11 Aug 2020 16:54:52

US3172038

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:05:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 16:52:44

US3172038

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:05:51
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
User entered '11 Aug 2020'	Mariete Rendon (b) (4)	11 Aug 2020 16:52:44
	(b) (4)	

US3172038

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:05:51
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
User entered '09:45'	Mariete Rendon (b) (4)	11 Aug 2020 16:52:44
	(b) (4)	

US3172038

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:05:51
User entered '11 Aug 2020 09:45'	System	11 Aug 2020 16:52:44

US3172038

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:05:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered '169.0' cm	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 16:52:44
DataPoint set to visible.	System	11 Aug 2020 16:11:22

US3172038

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:29

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:05:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered '104.7' kg	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 16:52:44
DataPoint set to visible.	System	11 Aug 2020 16:11:22

US3172038

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:29

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:05:51
Amendment Manager: User entered '36.65838'	System	16 Sep 2020 23:51:27
User entered '36.7'	System	11 Aug 2020 16:52:44
DataPoint set to visible.	System	11 Aug 2020 16:11:22

US3172038

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:29

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:05:51
User entered 'kg/m2'	System	11 Aug 2020 16:52:44
DataPoint set to visible.	System	11 Aug 2020 16:11:22

US3172038

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:05:51
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
User entered missing code ND - Not Done.	Mariete Rendon (b) (4)	11 Aug 2020 16:52:44
	(b) (4)	

US3172038

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:05:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	31 Aug 2020 13:19:02
Query 'Data is required. Please provide.' answered with 'PER GUIDELINES, ND' (Site from System).	Mariete Rendon (b) (4) (b) (4)	28 Aug 2020 20:55:41
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Aug 2020 16:52:44
User entered empty.	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 16:52:44

US3172038

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:05:51
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	11 Aug 2020 16:52:44
	(b) (4)	

US3172038

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:05:51
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
User entered missing code ND - Not Done.	Mariete Rendon (b) (4)	11 Aug 2020 16:52:44
	(b) (4)	

US3172038

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:05:51
User entered 'bpm'	System	11 Aug 2020 16:52:44

US3172038

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:05:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 16:52:44

US3172038

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:05:51
User entered 'breaths/min'	System	11 Aug 2020 16:52:44

US3172038

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:05:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 16:52:44

US3172038

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:05:51
User entered 'mmHg'	System	11 Aug 2020 16:52:44

US3172038

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:05:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 16:52:44

US3172038

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:29

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:05:51
User entered 'mmHg'	System	11 Aug 2020 16:52:44

US3172038

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:29

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:05:51

US3172038

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:29

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:05:51

US3172038

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:34:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:05:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	01 Oct 2020 21:52:34
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 16:52:54

US3172038

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:34:29

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:05:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered empty; reason for change Data Entry Error	Jessie Downs (b) (4) (b) (4)	01 Oct 2020 21:52:34
User entered '11 Aug 2020'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 16:52:54

US3172038

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:34:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:51
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
User entered '11 Aug 2020'	Mariete Rendon (b) (4)	11 Aug 2020 16:56:55
	(b) (4)	

US3172038

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 16:56:55

US3172038

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered 'Surgically sterile (SURGICALLY STERILE)'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 16:56:55

US3172038

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:34:29

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered empty.	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 16:56:55

US3172038

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:51
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
User entered 'UN UNK 2012'	Mariete Rendon (b) (4)	11 Aug 2020 16:56:55
	(b) (4)	

US3172038

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:34:29

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:51
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	11 Aug 2020 16:56:55
	(b) (4)	

US3172038

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered empty.	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 16:56:55

US3172038

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:34:29

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:51
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	11 Aug 2020 16:56:55
	(b) (4)	

US3172038

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:34:29

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 08:05:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 16:51:30

US3172038

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:34:29

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 08:05:51
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
User entered 'No (N)'	Mariete Rendon (b) (4)	11 Aug 2020 16:51:30
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:34:29

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 08:05:51
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
User entered 'Yes (Y)'	Mariete Rendon (b) (4)	11 Aug 2020 16:51:30
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:34:29

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 08:05:51
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
User entered 'No (N)'	Mariete Rendon (b) (4)	11 Aug 2020 16:51:30
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:34:29

[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 08:05:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 16:51:30

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:34:29

[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 08:05:51
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
User entered 'No (N)'	Mariete Rendon (b) (4)	11 Aug 2020 16:51:30
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:34:29

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 08:05:51
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
User entered 'No (N)'	Mariete Rendon (b) (4)	11 Aug 2020 16:51:30
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:05:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 16:51:30

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:34:29

[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 08:05:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 16:51:30

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:34:29

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 08:05:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 16:51:30

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:34:29

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 08:05:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 16:51:30

US3172038

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:34:29

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:05:51
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
User entered 'No (N)'	Mariete Rendon (b) (4)	11 Aug 2020 16:51:30
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:34:29

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:05:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered empty.	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 16:51:30

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:34:29

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:05:51
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	11 Aug 2020 16:51:30
	(b) (4)	

US3172038

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:05:51
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	11 Aug 2020 16:51:30
	(b) (4)	

US3172038

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:34:29

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 08:05:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered '0'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 16:51:30

US3172038

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:34:29

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 08:05:51
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	11 Aug 2020 16:51:30
	(b) (4)	

US3172038

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:34:29

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 08:05:51
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
User entered 'I'	Mariete Rendon (b) (4)	11 Aug 2020 16:51:30
	(b) (4)	

US3172038

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:05:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered '0'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 16:51:30

US3172038

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:34:29

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:05:51
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	11 Aug 2020 16:51:30
	(b) (4)	

US3172038

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:34:29

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:05:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered empty.	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 16:51:30

US3172038

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:34:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 16:58:52

US3172038

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered '11 Aug 2020'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 16:58:52

US3172038

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:34:29

[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 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered 'Clinic (Clinic)'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 16:58:52

US3172038

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:34:29

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User entered 'VISIT1'	System	11 Aug 2020 16:58:52

US3172038

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered '11 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	11 Aug 2020 14:59:26

US3172038

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:34:29

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 03:32:29
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:32:28
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	11 Aug 2020 14:59:26
User entered '102992' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	11 Aug 2020 14:59:26

US3172038

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	11 Aug 2020 14:59:26

US3172038

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:34:29

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 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 16:59:01

US3172038

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:34:29

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 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 16:59:01

US3172038

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 16:59:01

US3172038

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:34:29

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 16:59:01

US3172038

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:34:29

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 16:59:01

US3172038

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:34:29

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 16:59:35

US3172038

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:34:29

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 16:59:35

US3172038

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:34:29

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 16:59:35

US3172038

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:34:29

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 16:59:35

US3172038

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:29

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User accepted default value 'Pre-Dose (PREDOSE)'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 16:59:35

US3172038

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 16:59:35

US3172038

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered '11 Aug 2020'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 16:59:35

US3172038

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered '09:45'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 16:59:35

US3172038

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User entered '11 Aug 2020 09:45'	System	11 Aug 2020 16:59:35

US3172038

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered '36.8' C	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 16:59:35

US3172038

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered 'Oral (Oral)'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 16:59:35

US3172038

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered empty.	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 16:59:35

US3172038

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered '74'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 16:59:35

US3172038

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User entered 'bpm'	System	11 Aug 2020 16:59:35

US3172038

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered '14'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 16:59:35

US3172038

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User entered 'breaths/min'	System	11 Aug 2020 16:59:35

US3172038

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered '134'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 16:59:35

US3172038

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User entered 'mmHg'	System	11 Aug 2020 16:59:35

US3172038

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered '82'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 16:59:35

US3172038

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:29

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User entered 'mmHg'	System	11 Aug 2020 16:59:35

US3172038

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:34:29

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 16:59:35

US3172038

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:34:29

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 16:59:35

US3172038

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:29

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User accepted default value 'Post-Dose (POSTDOSE)'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 16:59:35

US3172038

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:29

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Aug 2020 17:48:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Aug 2020 17:48:01
User entered 'Yes (Y)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 17:48:01
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Aug 2020 16:59:35
User entered empty.	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 16:59:35

US3172038

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered '11 Aug 2020' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 17:48:01
User entered empty.	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 16:59:35

US3172038

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	17 Aug 2020 17:11:55
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		11 Aug 2020 17:48:01
User entered '12:35' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 17:48:01
User entered empty.	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 16:59:35

US3172038

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User entered '11 Aug 2020 12:35'	System	11 Aug 2020 17:48:01
User entered empty.	System	11 Aug 2020 16:59:35

US3172038

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered '36.9' C reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 17:48:01
User entered empty.	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 16:59:35

US3172038

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered 'Oral (Oral)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 17:48:01
User entered empty.	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 16:59:35

US3172038

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered empty.	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 16:59:35

US3172038

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered '84' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 17:48:01
User entered empty.	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 16:59:35

US3172038

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User entered 'bpm'	System	11 Aug 2020 17:48:01
User entered empty.	System	11 Aug 2020 16:59:35

US3172038

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered '16' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 17:48:01
User entered empty.	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 16:59:35

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User entered 'breaths/min'	System	11 Aug 2020 17:48:01
User entered empty.	System	11 Aug 2020 16:59:35

US3172038

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered '120' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 17:48:01
User entered empty.	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 16:59:35

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User entered 'mmHg'	System	11 Aug 2020 17:48:01
User entered empty.	System	11 Aug 2020 16:59:35

US3172038

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered '83' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 17:48:01
User entered empty.	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 16:59:35

US3172038

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:29

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User entered 'mmHg'	System	11 Aug 2020 17:48:01
User entered empty.	System	11 Aug 2020 16:59:35

US3172038

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:34:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	01 Oct 2020 21:52:50
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 16:59:42

US3172038

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:34:29

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered '11 Aug 2020' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	01 Oct 2020 21:52:50
User entered empty.	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 16:59:42

US3172038

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:34:29

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 16:11:44

US3172038

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:34:29

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered empty.	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 16:11:44

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:34:29

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 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered empty.	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 16:11:44

US3172038

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:34:29

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User entered 'MRNA-1273 OR PLACEBO'	System	11 Aug 2020 16:11:44

US3172038

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:34:29

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
User entered '11 Aug 2020'	Mariete Rendon (b) (4)	11 Aug 2020 16:11:44
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered '12:05'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 16:11:44

US3172038

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User entered '11 Aug 2020 12:05'	System	11 Aug 2020 16:11:44

US3172038

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered 'Left Arm (LEFT ARM)'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 16:11:44

US3172038

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:34:29

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User entered 'ONCE'	System	11 Aug 2020 16:11:44

US3172038

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:34:29

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User entered 'INTRAMUSCULAR'	System	11 Aug 2020 16:11:44

US3172038

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:34:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 17:00:26

US3172038

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:34:29

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered '11 Aug 2020'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 17:00:26

US3172038

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:34:29

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered '11:49'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 17:00:26

US3172038

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User entered '11 Aug 2020 11:49'	System	11 Aug 2020 17:00:26

US3172038

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:34:29

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered '11 Aug 2020'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 17:00:39

US3172038

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:34:29

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 17:00:39

US3172038

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:34:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 17:00:39

US3172038

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:34:29

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered '11:45'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 17:00:39

US3172038

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:34:29

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User entered '11 Aug 2020 11:45'	System	11 Aug 2020 17:00:39

US3172038

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:34:29

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 17:00:39

US3172038

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:34:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered 'No (N)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	16 Sep 2020 18:30:37
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 17:00:39

US3172038

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:34:29

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered empty; reason for change Data Entry Error	Mariete Rendon (b) (4) (b) (4)	16 Sep 2020 18:30:37
User entered '11:45'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 17:00:39

US3172038

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:34:29

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User entered empty.	System	16 Sep 2020 18:30:37
User entered '11 Aug 2020 11:45'	System	11 Aug 2020 17:00:39

US3172038

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	11 Aug 2020 17:48:08

US3172038

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:34:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User entered '1'	System	11 Aug 2020 17:48:08

US3172038

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
Data entry locked.	System	11 Aug 2020 16:11:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 16:11:44

US3172038

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:34:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-11T12:40:51', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: 'd6b72424-79a5-41a1-91bd-ab85994bfe63' User entered 'Yes (Y)'	System	11 Aug 2020 16:41:07
	System	11 Aug 2020 16:41:07

US3172038

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:34:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-11T12:40:58', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: 'd6b72424-79a5-41a1-91bd-ab85994bfe63' User entered '98.5'	System	11 Aug 2020 16:41:07
	System	11 Aug 2020 16:41:07

US3172038

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-11T12:41:01', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: 'd6b72424-79a5-41a1-91bd-ab85994bfe63'	System	11 Aug 2020 16:41:07
User entered 'No (N)'	System	11 Aug 2020 16:41:07

US3172038

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:34:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-11T12:41:04', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: 'd6b72424-79a5-41a1-91bd-ab85994bfe63' User entered '11 Aug 2020 12:41'	System	11 Aug 2020 16:41:07
	System	11 Aug 2020 16:41:07

US3172038

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:34:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
User entered '11 Aug 2020 12:25'	System	11 Aug 2020 16:11:44

US3172038

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:34:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
User entered '11 Aug 2020 14:55'	System	11 Aug 2020 16:11:44

US3172038

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
Data entry locked.	System	11 Aug 2020 16:11:44
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 16:11:44

US3172038

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:34:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-11T21:26:12', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: 'a124f27d-30da-42a5-95d0-04cd805ee011' User entered 'Yes (Y)'	System	12 Aug 2020 01:26:34
	System	12 Aug 2020 01:26:34

US3172038

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:34:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-11T21:26:19', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: 'a124f27d-30da-42a5-95d0-04cd805ee011' User entered '97.4'	System	12 Aug 2020 01:26:34
	System	12 Aug 2020 01:26:34

US3172038

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-11T21:26:25', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: 'a124f27d-30da-42a5-95d0-04cd805ee011' User entered 'No (N)'	System	12 Aug 2020 01:26:34
	System	12 Aug 2020 01:26:34

US3172038

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:34:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-11T21:26:28', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: 'a124f27d-30da-42a5-95d0-04cd805ee011' User entered '11 Aug 2020 21:26'	System	12 Aug 2020 01:26:34
	System	12 Aug 2020 01:26:34

US3172038

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:34:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
User entered '11 Aug 2020 15:50'	System	11 Aug 2020 16:11:44

US3172038

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:34:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 16:11:44

US3172038

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
Data entry locked.	System	11 Aug 2020 16:11:44
User entered 'Day 2'	System	11 Aug 2020 16:11:44

US3172038

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:34:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-12T22:02:45', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: 'e7d6a784-348c-429a-8c3d-40d662d4c6c3' User entered 'Yes (Y)'	System	13 Aug 2020 02:03:03
	System	13 Aug 2020 02:03:03

US3172038

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:34:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEE6D59)', Time: '2020-08-12T22:02:50', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: 'e7d6a784-348c-429a-8c3d-40d662d4c6c3' User entered '98.7'	System	13 Aug 2020 02:03:03
	System	13 Aug 2020 02:03:03

US3172038

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-12T22:02:56', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: 'e7d6a784-348c-429a-8c3d-40d662d4c6c3' User entered 'No (N)'	System	13 Aug 2020 02:03:03
	System	13 Aug 2020 02:03:03

US3172038

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:34:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-12T22:03:00', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: 'e7d6a784-348c-429a-8c3d-40d662d4c6c3' User entered '12 Aug 2020 22:03'	System	13 Aug 2020 02:03:03
	System	13 Aug 2020 02:03:03

US3172038

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:34:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 16:11:44

US3172038

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:34:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 16:11:44

US3172038

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
Data entry locked.	System	11 Aug 2020 16:11:44
User entered 'Day 3'	System	11 Aug 2020 16:11:44

US3172038

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:34:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-13T19:44:13', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '5be11535-f8a1-4756-9235-fe3840c102ce' User entered 'Yes (Y)'	System	13 Aug 2020 23:44:28
	System	13 Aug 2020 23:44:28

US3172038

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:34:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-13T19:44:18', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '5be11535-f8a1-4756-9235-fe3840c102ce' User entered '98.4'	System	13 Aug 2020 23:44:28
	System	13 Aug 2020 23:44:28

US3172038

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-13T19:44:24', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '5be11535-f8a1-4756-9235-fe3840c102ce'	System	13 Aug 2020 23:44:28
User entered 'No (N)'	System	13 Aug 2020 23:44:28

US3172038

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:34:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-13T19:44:27', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '5be11535-f8a1-4756-9235-fe3840c102ce' User entered '13 Aug 2020 19:44'	System	13 Aug 2020 23:44:28
	System	13 Aug 2020 23:44:28

US3172038

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:34:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 16:11:44

US3172038

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:34:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 16:11:44

US3172038

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
Data entry locked.	System	11 Aug 2020 16:11:44
User entered 'Day 4'	System	11 Aug 2020 16:11:44

US3172038

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:34:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-14T22:33:47', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '12693445-811a-4ea6-a56d-203c585bf158' User entered 'Yes (Y)'	System	15 Aug 2020 02:34:00
	System	15 Aug 2020 02:34:00

US3172038

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:34:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-14T22:33:51', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '12693445-811a-4ea6-a56d-203c585bf158' User entered '98.4'	System	15 Aug 2020 02:34:00
	System	15 Aug 2020 02:34:00

US3172038

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-14T22:33:55', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '12693445-811a-4ea6-a56d-203c585bf158'	System	15 Aug 2020 02:34:00
User entered 'No (N)'	System	15 Aug 2020 02:34:00

US3172038

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:34:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-14T22:33:57', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '12693445-811a-4ea6-a56d-203c585bf158'	System	15 Aug 2020 02:34:00
User entered '14 Aug 2020 22:33'	System	15 Aug 2020 02:34:00

US3172038

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:34:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 16:11:44

US3172038

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:34:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 16:11:44

US3172038

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
Data entry locked.	System	11 Aug 2020 16:11:44
User entered 'Day 5'	System	11 Aug 2020 16:11:44

US3172038

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:34:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-15T23:59:26', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: 'b28daef1-069a-4a70-a807-8d7163abe142' User entered 'Yes (Y)'	System	16 Aug 2020 03:59:39
	System	16 Aug 2020 03:59:39

US3172038

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:34:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-15T23:59:32', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: 'b28daef1-069a-4a70-a807-8d7163abe142' User entered '97.4'	System	16 Aug 2020 03:59:39
	System	16 Aug 2020 03:59:39

US3172038

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-15T23:59:35', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: 'b28daef1-069a-4a70-a807-8d7163abe142'	System	16 Aug 2020 03:59:39
User entered 'No (N)'	System	16 Aug 2020 03:59:39

US3172038

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:34:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-15T23:59:38', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: 'b28daef1-069a-4a70-a807-8d7163abe142'	System	16 Aug 2020 03:59:39
User entered '15 Aug 2020 23:59'	System	16 Aug 2020 03:59:39

US3172038

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:34:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 16:11:44

US3172038

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:34:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 16:11:44

US3172038

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
Data entry locked.	System	11 Aug 2020 16:11:44
User entered 'Day 6'	System	11 Aug 2020 16:11:44

US3172038

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:34:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-16T22:41:24', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '057bebf5-5830-4863-b245-336adb069864' User entered 'Yes (Y)'	System	17 Aug 2020 02:41:38
	System	17 Aug 2020 02:41:38

US3172038

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:34:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-16T22:41:28', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '057bebf5-5830-4863-b245-336adb069864' User entered '98.7'	System	17 Aug 2020 02:41:38
	System	17 Aug 2020 02:41:38

US3172038

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-16T22:41:30', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '057bebf5-5830-4863-b245-336adb069864' User entered 'No (N)'	System	17 Aug 2020 02:41:38
	System	17 Aug 2020 02:41:38

US3172038

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:34:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-16T22:41:35', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '057bebf5-5830-4863-b245-336adb069864' User entered '16 Aug 2020 22:41'	System	17 Aug 2020 02:41:38
	System	17 Aug 2020 02:41:38

US3172038

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:34:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 16:11:44

US3172038

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:34:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 16:11:44

US3172038

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
Data entry locked.	System	11 Aug 2020 16:11:44
User entered 'Day 7'	System	11 Aug 2020 16:11:44

US3172038

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:34:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-18T05:10:36', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: 'a878cb07-ddf6-4747-8eed-e7283a44d0a4'	System	18 Aug 2020 09:10:49
User entered 'Yes (Y)'	System	18 Aug 2020 09:10:49

US3172038

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:34:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-18T05:10:42', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: 'a878cb07-ddf6-4747-8eed-e7283a44d0a4' User entered '97.4'	System	18 Aug 2020 09:10:49
	System	18 Aug 2020 09:10:49

US3172038

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-18T05:10:44', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: 'a878cb07-ddf6-4747-8eed-e7283a44d0a4'	System	18 Aug 2020 09:10:49
User entered 'No (N)'	System	18 Aug 2020 09:10:49

US3172038

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:34:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-18T05:10:47', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: 'a878cb07-ddf6-4747-8eed-e7283a44d0a4'	System	18 Aug 2020 09:10:49
User entered '18 Aug 2020 05:10'	System	18 Aug 2020 09:10:49

US3172038

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:34:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 16:11:44

US3172038

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:34:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 16:11:44

US3172038

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
Data entry locked.	System	11 Aug 2020 16:11:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 16:11:44

US3172038

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:34:29

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 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-11T12:41:14', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: 'c1997755-4df1-412d-821c-d39a8742a7dc'	System	11 Aug 2020 16:41:32
User entered 'None (1)'	System	11 Aug 2020 16:41:32

US3172038

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:34:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-11T12:41:18', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: 'c1997755-4df1-412d-821c-d39a8742a7dc' User entered 'No (N)'	System	11 Aug 2020 16:41:32
	System	11 Aug 2020 16:41:32

US3172038

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-11T12:41:21', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: 'c1997755-4df1-412d-821c-d39a8742a7dc' User entered 'No (N)'	System	11 Aug 2020 16:41:32
	System	11 Aug 2020 16:41:32

US3172038

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:34:29

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 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-11T12:41:27', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: 'c1997755-4df1-412d-821c-d39a8742a7dc' User entered 'None (1)'	System	11 Aug 2020 16:41:32
	System	11 Aug 2020 16:41:32

US3172038

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:34:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-11T12:41:30', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: 'c1997755-4df1-412d-821c-d39a8742a7dc' User entered '11 Aug 2020 12:41'	System	11 Aug 2020 16:41:32
	System	11 Aug 2020 16:41:32

US3172038

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:34:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
User entered '11 Aug 2020 12:25'	System	11 Aug 2020 16:11:44

US3172038

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:34:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
User entered '11 Aug 2020 14:55'	System	11 Aug 2020 16:11:44

US3172038

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
Data entry locked.	System	11 Aug 2020 16:11:44
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 16:11:44

US3172038

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:34:29

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 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-11T21:26:33', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '1d852c77-746b-4324-aea7-4438aec149ef' User entered 'None (1)'	System	12 Aug 2020 01:26:53
	System	12 Aug 2020 01:26:53

US3172038

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:34:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-11T21:26:36', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '1d852c77-746b-4324-aea7-4438aec149ef' User entered 'No (N)'	System	12 Aug 2020 01:26:53
	System	12 Aug 2020 01:26:53

US3172038

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-11T21:26:41', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '1d852c77-746b-4324-aea7-4438aec149ef' User entered 'No (N)'	System	12 Aug 2020 01:26:53
	System	12 Aug 2020 01:26:53

US3172038

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:34:29

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 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-11T21:26:48', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '1d852c77-746b-4324-aea7-4438aec149ef' User entered 'None (1)'	System	12 Aug 2020 01:26:53
	System	12 Aug 2020 01:26:53

US3172038

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:34:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-11T21:26:50', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '1d852c77-746b-4324-aea7-4438aec149ef' User entered '11 Aug 2020 21:26'	System	12 Aug 2020 01:26:53
	System	12 Aug 2020 01:26:53

US3172038

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:34:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
User entered '11 Aug 2020 15:50'	System	11 Aug 2020 16:11:44

US3172038

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:34:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 16:11:44

US3172038

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
Data entry locked.	System	11 Aug 2020 16:11:44
User entered 'Day 2'	System	11 Aug 2020 16:11:44

US3172038

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:34:29

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 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-12T22:03:04', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '1b21dc0c-87ee-4160-b333-ddb779bf8104' User entered 'None (1)'	System	13 Aug 2020 02:03:17
	System	13 Aug 2020 02:03:17

US3172038

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:34:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-12T22:03:06', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '1b21dc0c-87ee-4160-b333-ddb779bf8104' User entered 'No (N)'	System	13 Aug 2020 02:03:17
	System	13 Aug 2020 02:03:17

US3172038

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-12T22:03:08', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '1b21dc0c-87ee-4160-b333-ddb779bf8104' User entered 'No (N)'	System	13 Aug 2020 02:03:17
	System	13 Aug 2020 02:03:17

US3172038

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:34:29

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 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-12T22:03:13', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '1b21dc0c-87ee-4160-b333-ddb779bf8104' User entered 'None (1)'	System	13 Aug 2020 02:03:17
	System	13 Aug 2020 02:03:17

US3172038

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:34:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-12T22:03:15', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '1b21dc0c-87ee-4160-b333-ddb779bf8104' User entered '12 Aug 2020 22:03'	System	13 Aug 2020 02:03:17
	System	13 Aug 2020 02:03:17

US3172038

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:34:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 16:11:44

US3172038

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:34:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 16:11:44

US3172038

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
Data entry locked.	System	11 Aug 2020 16:11:44
User entered 'Day 3'	System	11 Aug 2020 16:11:44

US3172038

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:34:29

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 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-13T19:44:30', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '9418e0ea-0f70-4286-9f5c-8252f5c717f1' User entered 'None (1)'	System	13 Aug 2020 23:44:41
	System	13 Aug 2020 23:44:41

US3172038

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:34:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-13T19:44:33', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '9418e0ea-0f70-4286-9f5c-8252f5c717f1' User entered 'No (N)'	System	13 Aug 2020 23:44:41
	System	13 Aug 2020 23:44:41

US3172038

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-13T19:44:34', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '9418e0ea-0f70-4286-9f5c-8252f5c717f1' User entered 'No (N)'	System	13 Aug 2020 23:44:41
	System	13 Aug 2020 23:44:41

US3172038

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:34:29

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 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-13T19:44:36', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '9418e0ea-0f70-4286-9f5c-8252f5c717f1' User entered 'None (1)'	System	13 Aug 2020 23:44:41
	System	13 Aug 2020 23:44:41

US3172038

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:34:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-13T19:44:39', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '9418e0ea-0f70-4286-9f5c-8252f5c717f1' User entered '13 Aug 2020 19:44'	System	13 Aug 2020 23:44:41
	System	13 Aug 2020 23:44:41

US3172038

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:34:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 16:11:44

US3172038

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:34:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 16:11:44

US3172038

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
Data entry locked.	System	11 Aug 2020 16:11:44
User entered 'Day 4'	System	11 Aug 2020 16:11:44

US3172038

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:34:29

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 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-14T22:34:01', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '774c46af-1d42-44d8-b2da-44751d86f860'	System	15 Aug 2020 02:34:11
User entered 'None (1)'	System	15 Aug 2020 02:34:11

US3172038

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-14T22:34:03', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '774c46af-1d42-44d8-b2da-44751d86f860'	System	15 Aug 2020 02:34:11
User entered 'No (N)'	System	15 Aug 2020 02:34:11

US3172038

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-14T22:34:05', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '774c46af-1d42-44d8-b2da-44751d86f860'	System	15 Aug 2020 02:34:11
User entered 'No (N)'	System	15 Aug 2020 02:34:11

US3172038

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:34:29

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 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-14T22:34:07', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '774c46af-1d42-44d8-b2da-44751d86f860'	System	15 Aug 2020 02:34:11
User entered 'None (1)'	System	15 Aug 2020 02:34:11

US3172038

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:34:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-14T22:34:09', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '774c46af-1d42-44d8-b2da-44751d86f860'	System	15 Aug 2020 02:34:11
User entered '14 Aug 2020 22:34'	System	15 Aug 2020 02:34:11

US3172038

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:34:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 16:11:44

US3172038

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:34:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 16:11:44

US3172038

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
Data entry locked.	System	11 Aug 2020 16:11:44
User entered 'Day 5'	System	11 Aug 2020 16:11:44

US3172038

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:34:29

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 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-15T23:59:42', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '96a92508-8ca2-4afc-b0b9-934c344a3e60'	System	16 Aug 2020 03:59:52
User entered 'None (1)'	System	16 Aug 2020 03:59:52

US3172038

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-15T23:59:44', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '96a92508-8ca2-4afc-b0b9-934c344a3e60' User entered 'No (N)'	System	16 Aug 2020 03:59:52
	System	16 Aug 2020 03:59:52

US3172038

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-15T23:59:45', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '96a92508-8ca2-4afc-b0b9-934c344a3e60'	System	16 Aug 2020 03:59:52
User entered 'No (N)'	System	16 Aug 2020 03:59:52

US3172038

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:34:29

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 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-15T23:59:47', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '96a92508-8ca2-4afc-b0b9-934c344a3e60'	System	16 Aug 2020 03:59:52
User entered 'None (1)'	System	16 Aug 2020 03:59:52

US3172038

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:34:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-15T23:59:49', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '96a92508-8ca2-4afc-b0b9-934c344a3e60' User entered '15 Aug 2020 23:59'	System	16 Aug 2020 03:59:52
	System	16 Aug 2020 03:59:52

US3172038

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:34:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 16:11:44

US3172038

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:34:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 16:11:44

US3172038

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
Data entry locked.	System	11 Aug 2020 16:11:44
User entered 'Day 6'	System	11 Aug 2020 16:11:44

US3172038

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:34:29

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 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-16T22:41:38', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '049e5bf6-1f25-438d-b9c5-a3b8ab2b00bd' User entered 'None (1)'	System	17 Aug 2020 02:41:52
	System	17 Aug 2020 02:41:52

US3172038

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:34:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-16T22:41:42', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '049e5bf6-1f25-438d-b9c5-a3b8ab2b00bd' User entered 'No (N)'	System	17 Aug 2020 02:41:52
	System	17 Aug 2020 02:41:52

US3172038

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-16T22:41:45', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '049e5bf6-1f25-438d-b9c5-a3b8ab2b00bd' User entered 'No (N)'	System	17 Aug 2020 02:41:52
	System	17 Aug 2020 02:41:52

US3172038

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:34:29

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 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEE6D59)', Time: '2020-08-16T22:41:48', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '049e5bf6-1f25-438d-b9c5-a3b8ab2b00bd' User entered 'None (1)'	System	17 Aug 2020 02:41:52
	System	17 Aug 2020 02:41:52

US3172038

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:34:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-16T22:41:50', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '049e5bf6-1f25-438d-b9c5-a3b8ab2b00bd' User entered '16 Aug 2020 22:41'	System	17 Aug 2020 02:41:52
	System	17 Aug 2020 02:41:52

US3172038

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:34:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 16:11:44

US3172038

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:34:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 16:11:44

US3172038

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
Data entry locked.	System	11 Aug 2020 16:11:44
User entered 'Day 7'	System	11 Aug 2020 16:11:44

US3172038

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:34:29

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 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-18T05:10:50', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '75b7aa83-e27a-4b65-87f8-9e0bc054dbb3' User entered 'None (1)'	System	18 Aug 2020 09:10:59
	System	18 Aug 2020 09:10:59

US3172038

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:34:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-18T05:10:52', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '75b7aa83-e27a-4b65-87f8-9e0bc054dbb3' User entered 'No (N)'	System	18 Aug 2020 09:10:59
	System	18 Aug 2020 09:10:59

US3172038

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-18T05:10:54', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '75b7aa83-e27a-4b65-87f8-9e0bc054dbb3' User entered 'No (N)'	System	18 Aug 2020 09:10:59
	System	18 Aug 2020 09:10:59

US3172038

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:34:29

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 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-18T05:10:55', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '75b7aa83-e27a-4b65-87f8-9e0bc054dbb3' User entered 'None (1)'	System	18 Aug 2020 09:10:59
	System	18 Aug 2020 09:10:59

US3172038

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:34:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-18T05:10:57', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '75b7aa83-e27a-4b65-87f8-9e0bc054dbb3' User entered '18 Aug 2020 05:10'	System	18 Aug 2020 09:10:59
	System	18 Aug 2020 09:10:59

US3172038

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:34:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 16:11:44

US3172038

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:34:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 16:11:44

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
Data entry locked.	System	11 Aug 2020 16:11:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 16:11:44

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:34:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEE6D59)', Time: '2020-08-11T12:41:36', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: 'e68fd4c1-feeaa-4669-b81d-e1239d141cf4'	System	11 Aug 2020 16:41:57
User entered 'None (0)'	System	11 Aug 2020 16:41:57

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:34:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-11T12:41:38', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: 'e68fd4c1-feeaa-4669-b81d-e1239d141cf4' User entered 'None (0)'	System	11 Aug 2020 16:41:57
	System	11 Aug 2020 16:41:57

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:34:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-11T12:41:40', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: 'e68fd4c1-feeaa-4669-b81d-e1239d141cf4' User entered 'None (0)'	System	11 Aug 2020 16:41:57
	System	11 Aug 2020 16:41:57

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:34:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-11T12:41:41', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: 'e68fd4c1-feeaa-4669-b81d-e1239d141cf4' User entered 'None (0)'	System	11 Aug 2020 16:41:57
	System	11 Aug 2020 16:41:57

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:34:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-11T12:41:43', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: 'e68fd4c1-feeaa-4669-b81d-e1239d141cf4' User entered 'None (0)'	System	11 Aug 2020 16:41:57
	System	11 Aug 2020 16:41:57

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:34:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-11T12:41:45', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: 'e68fd4c1-feeaa-4669-b81d-e1239d141cf4'	System	11 Aug 2020 16:41:57
User entered 'None (0)'	System	11 Aug 2020 16:41:57

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:34:29

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 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-11T12:41:52', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: 'e68fd4c1-feeaa-4669-b81d-e1239d141cf4'	System	11 Aug 2020 16:41:57
User entered 'No (N)'	System	11 Aug 2020 16:41:57

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:34:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-11T12:41:55', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: 'e68fd4c1-feeaa-4669-b81d-e1239d141cf4' User entered '11 Aug 2020 12:41'	System	11 Aug 2020 16:41:57
	System	11 Aug 2020 16:41:57

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:34:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
User entered '11 Aug 2020 12:25'	System	11 Aug 2020 16:11:44

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:34:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
User entered '11 Aug 2020 14:55'	System	11 Aug 2020 16:11:44

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
Data entry locked.	System	11 Aug 2020 16:11:44
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 16:11:44

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:34:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-11T21:26:56', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: 'fdf59d1d-5451-4487-8511-6055432247a5' User entered 'None (0)'	System	12 Aug 2020 01:27:21
	System	12 Aug 2020 01:27:21

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:34:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-11T21:26:58', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: 'fdf59d1d-5451-4487-8511-6055432247a5' User entered 'None (0)'	System	12 Aug 2020 01:27:21
	System	12 Aug 2020 01:27:21

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:34:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-11T21:27:00', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: 'fdf59d1d-5451-4487-8511-6055432247a5' User entered 'None (0)'	System	12 Aug 2020 01:27:21
	System	12 Aug 2020 01:27:21

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:34:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-11T21:27:06', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: 'fdf59d1d-5451-4487-8511-6055432247a5' User entered 'None (0)'	System	12 Aug 2020 01:27:21
	System	12 Aug 2020 01:27:21

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:34:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-11T21:27:09', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: 'fdf59d1d-5451-4487-8511-6055432247a5' User entered 'None (0)'	System	12 Aug 2020 01:27:21
	System	12 Aug 2020 01:27:21

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:34:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-11T21:27:13', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: 'fdf59d1d-5451-4487-8511-6055432247a5' User entered 'None (0)'	System	12 Aug 2020 01:27:21
	System	12 Aug 2020 01:27:21

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:34:29

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 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-11T21:27:17', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: 'fdf59d1d-5451-4487-8511-6055432247a5' User entered 'No (N)'	System	12 Aug 2020 01:27:21
	System	12 Aug 2020 01:27:21

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:34:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-11T21:27:19', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: 'fdf59d1d-5451-4487-8511-6055432247a5' User entered '11 Aug 2020 21:27'	System	12 Aug 2020 01:27:21
	System	12 Aug 2020 01:27:21

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:34:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
User entered '11 Aug 2020 15:50'	System	11 Aug 2020 16:11:44

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:34:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 16:11:44

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
Data entry locked.	System	11 Aug 2020 16:11:44
User entered 'Day 2'	System	11 Aug 2020 16:11:44

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:34:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-12T22:03:20', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '2dab2700-1a7b-401c-a8e9-a0db94a268a2' User entered 'None (0)'	System	13 Aug 2020 02:03:43
	System	13 Aug 2020 02:03:43

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:34:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-12T22:03:23', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '2dab2700-1a7b-401c-a8e9-a0db94a268a2' User entered 'None (0)'	System	13 Aug 2020 02:03:43
	System	13 Aug 2020 02:03:43

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:34:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-12T22:03:27', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '2dab2700-1a7b-401c-a8e9-a0db94a268a2' User entered 'None (0)'	System	13 Aug 2020 02:03:43
	System	13 Aug 2020 02:03:43

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:34:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-12T22:03:29', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '2dab2700-1a7b-401c-a8e9-a0db94a268a2' User entered 'None (0)'	System	13 Aug 2020 02:03:43
	System	13 Aug 2020 02:03:43

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:34:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-12T22:03:31', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '2dab2700-1a7b-401c-a8e9-a0db94a268a2' User entered 'None (0)'	System	13 Aug 2020 02:03:43
	System	13 Aug 2020 02:03:43

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:34:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-12T22:03:33', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '2dab2700-1a7b-401c-a8e9-a0db94a268a2' User entered 'None (0)'	System	13 Aug 2020 02:03:43
	System	13 Aug 2020 02:03:43

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:34:29

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 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-12T22:03:38', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '2dab2700-1a7b-401c-a8e9-a0db94a268a2' User entered 'No (N)'	System	13 Aug 2020 02:03:43
	System	13 Aug 2020 02:03:43

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:34:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-12T22:03:40', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '2dab2700-1a7b-401c-a8e9-a0db94a268a2'	System	13 Aug 2020 02:03:43
User entered '12 Aug 2020 22:03'	System	13 Aug 2020 02:03:43

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:34:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 16:11:44

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:34:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 16:11:44

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
Data entry locked.	System	11 Aug 2020 16:11:44
User entered 'Day 3'	System	11 Aug 2020 16:11:44

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:34:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-13T19:44:43', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '8a96a450-5152-4336-a4a7-60fbe3154e77' User entered 'None (0)'	System	13 Aug 2020 23:44:58
	System	13 Aug 2020 23:44:58

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:34:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-13T19:44:44', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '8a96a450-5152-4336-a4a7-60fbe3154e77' User entered 'None (0)'	System	13 Aug 2020 23:44:58
	System	13 Aug 2020 23:44:58

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:34:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-13T19:44:46', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '8a96a450-5152-4336-a4a7-60fbe3154e77' User entered 'None (0)'	System	13 Aug 2020 23:44:58
	System	13 Aug 2020 23:44:58

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:34:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-13T19:44:47', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '8a96a450-5152-4336-a4a7-60fbe3154e77' User entered 'None (0)'	System	13 Aug 2020 23:44:58
	System	13 Aug 2020 23:44:58

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:34:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-13T19:44:49', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '8a96a450-5152-4336-a4a7-60fbe3154e77' User entered 'None (0)'	System	13 Aug 2020 23:44:58
	System	13 Aug 2020 23:44:58

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:34:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-13T19:44:51', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '8a96a450-5152-4336-a4a7-60fbe3154e77' User entered 'None (0)'	System	13 Aug 2020 23:44:58
	System	13 Aug 2020 23:44:58

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:34:29

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 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-13T19:44:54', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '8a96a450-5152-4336-a4a7-60fbe3154e77'	System	13 Aug 2020 23:44:58
User entered 'No (N)'	System	13 Aug 2020 23:44:58

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:34:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-13T19:44:56', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '8a96a450-5152-4336-a4a7-60fbe3154e77' User entered '13 Aug 2020 19:44'	System	13 Aug 2020 23:44:58
	System	13 Aug 2020 23:44:58

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:34:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 16:11:44

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:34:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 16:11:44

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
Data entry locked.	System	11 Aug 2020 16:11:44
User entered 'Day 4'	System	11 Aug 2020 16:11:44

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:34:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-14T22:34:14', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '5377d3e7-6bb0-4bf2-887c-b9595d93ef10' User entered 'None (0)'	System	15 Aug 2020 02:34:29
	System	15 Aug 2020 02:34:29

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:34:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-14T22:34:16', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '5377d3e7-6bb0-4bf2-887c-b9595d93ef10' User entered 'None (0)'	System	15 Aug 2020 02:34:29
	System	15 Aug 2020 02:34:29

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:34:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-14T22:34:18', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '5377d3e7-6bb0-4bf2-887c-b9595d93ef10' User entered 'None (0)'	System	15 Aug 2020 02:34:29
	System	15 Aug 2020 02:34:29

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:34:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-14T22:34:19', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '5377d3e7-6bb0-4bf2-887c-b9595d93ef10' User entered 'None (0)'	System	15 Aug 2020 02:34:29
	System	15 Aug 2020 02:34:29

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:34:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-14T22:34:21', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '5377d3e7-6bb0-4bf2-887c-b9595d93ef10' User entered 'None (0)'	System	15 Aug 2020 02:34:29
	System	15 Aug 2020 02:34:29

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:34:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-14T22:34:22', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '5377d3e7-6bb0-4bf2-887c-b9595d93ef10' User entered 'None (0)'	System	15 Aug 2020 02:34:29
	System	15 Aug 2020 02:34:29

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:34:29

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 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-14T22:34:25', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '5377d3e7-6bb0-4bf2-887c-b9595d93ef10' User entered 'No (N)'	System	15 Aug 2020 02:34:29
	System	15 Aug 2020 02:34:29

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:34:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-14T22:34:27', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '5377d3e7-6bb0-4bf2-887c-b9595d93ef10' User entered '14 Aug 2020 22:34'	System	15 Aug 2020 02:34:29
	System	15 Aug 2020 02:34:29

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:34:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 16:11:44

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:34:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 16:11:44

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
Data entry locked.	System	11 Aug 2020 16:11:44
User entered 'Day 5'	System	11 Aug 2020 16:11:44

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:34:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-15T23:59:52', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: 'a9f99d0c-1703-4294-8abb-441ad29394b7' User entered 'None (0)'	System	16 Aug 2020 04:00:09
	System	16 Aug 2020 04:00:09

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:34:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-15T23:59:54', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: 'a9f99d0c-1703-4294-8abb-441ad29394b7' User entered 'None (0)'	System	16 Aug 2020 04:00:09
	System	16 Aug 2020 04:00:09

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:34:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-15T23:59:56', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: 'a9f99d0c-1703-4294-8abb-441ad29394b7' User entered 'None (0)'	System	16 Aug 2020 04:00:09
	System	16 Aug 2020 04:00:09

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:34:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-15T23:59:57', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: 'a9f99d0c-1703-4294-8abb-441ad29394b7' User entered 'None (0)'	System	16 Aug 2020 04:00:09
	System	16 Aug 2020 04:00:09

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:34:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-15T23:59:59', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: 'a9f99d0c-1703-4294-8abb-441ad29394b7' User entered 'None (0)'	System	16 Aug 2020 04:00:09
	System	16 Aug 2020 04:00:09

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:34:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-16T00:00:00', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: 'a9f99d0c-1703-4294-8abb-441ad29394b7' User entered 'None (0)'	System	16 Aug 2020 04:00:09
	System	16 Aug 2020 04:00:09

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:34:29

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 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-16T00:00:04', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: 'a9f99d0c-1703-4294-8abb-441ad29394b7' User entered 'No (N)'	System	16 Aug 2020 04:00:09
	System	16 Aug 2020 04:00:09

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:34:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-16T00:00:06', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: 'a9f99d0c-1703-4294-8abb-441ad29394b7' User entered '16 Aug 2020 00:00'	System	16 Aug 2020 04:00:09
	System	16 Aug 2020 04:00:09

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:34:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 16:11:44

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:34:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 16:11:44

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
Data entry locked.	System	11 Aug 2020 16:11:44
User entered 'Day 6'	System	11 Aug 2020 16:11:44

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:34:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-16T22:41:53', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '7a90e5ba-1aee-44f8-a17c-6c9bbf1394cb' User entered 'None (0)'	System	17 Aug 2020 02:42:11
	System	17 Aug 2020 02:42:11

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:34:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-16T22:41:55', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '7a90e5ba-1aee-44f8-a17c-6c9bbf1394cb' User entered 'None (0)'	System	17 Aug 2020 02:42:11
	System	17 Aug 2020 02:42:11

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:34:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-16T22:41:57', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '7a90e5ba-1aee-44f8-a17c-6c9bbf1394cb' User entered 'None (0)'	System	17 Aug 2020 02:42:11
	System	17 Aug 2020 02:42:11

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:34:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-16T22:41:59', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '7a90e5ba-1aee-44f8-a17c-6c9bbf1394cb' User entered 'None (0)'	System	17 Aug 2020 02:42:11
	System	17 Aug 2020 02:42:11

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:34:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-16T22:42:00', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '7a90e5ba-1aee-44f8-a17c-6c9bbf1394cb' User entered 'None (0)'	System	17 Aug 2020 02:42:11
	System	17 Aug 2020 02:42:11

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:34:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-16T22:42:01', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '7a90e5ba-1aee-44f8-a17c-6c9bbf1394cb' User entered 'None (0)'	System	17 Aug 2020 02:42:11
	System	17 Aug 2020 02:42:11

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:34:29

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 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEE6D59)', Time: '2020-08-16T22:42:05', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '7a90e5ba-1aee-44f8-a17c-6c9bbf1394cb' User entered 'No (N)'	System	17 Aug 2020 02:42:11
	System	17 Aug 2020 02:42:11

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:34:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-16T22:42:07', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '7a90e5ba-1aee-44f8-a17c-6c9bbf1394cb' User entered '16 Aug 2020 22:42'	System	17 Aug 2020 02:42:11
	System	17 Aug 2020 02:42:11

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:34:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 16:11:44

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:34:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 16:11:44

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
Data entry locked.	System	11 Aug 2020 16:11:44
User entered 'Day 7'	System	11 Aug 2020 16:11:44

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:34:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-18T05:11:00', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: 'b6c1a049-b5c8-4cb2-8545-f917bb3df267' User entered 'None (0)'	System	18 Aug 2020 09:11:13
	System	18 Aug 2020 09:11:13

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:34:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-18T05:11:01', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: 'b6c1a049-b5c8-4cb2-8545-f917bb3df267' User entered 'None (0)'	System	18 Aug 2020 09:11:13
	System	18 Aug 2020 09:11:13

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:34:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-18T05:11:03', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: 'b6c1a049-b5c8-4cb2-8545-f917bb3df267' User entered 'None (0)'	System	18 Aug 2020 09:11:13
	System	18 Aug 2020 09:11:13

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:34:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-18T05:11:04', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: 'b6c1a049-b5c8-4cb2-8545-f917bb3df267' User entered 'None (0)'	System	18 Aug 2020 09:11:13
	System	18 Aug 2020 09:11:13

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:34:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-18T05:11:06', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: 'b6c1a049-b5c8-4cb2-8545-f917bb3df267' User entered 'None (0)'	System	18 Aug 2020 09:11:13
	System	18 Aug 2020 09:11:13

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:34:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-18T05:11:07', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: 'b6c1a049-b5c8-4cb2-8545-f917bb3df267' User entered 'None (0)'	System	18 Aug 2020 09:11:13
	System	18 Aug 2020 09:11:13

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:34:29

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 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-18T05:11:09', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: 'b6c1a049-b5c8-4cb2-8545-f917bb3df267'	System	18 Aug 2020 09:11:13
User entered 'No (N)'	System	18 Aug 2020 09:11:13

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:34:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-08-18T05:11:11', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: 'b6c1a049-b5c8-4cb2-8545-f917bb3df267' User entered '18 Aug 2020 05:11'	System	18 Aug 2020 09:11:13
	System	18 Aug 2020 09:11:13

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:34:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 16:11:44

US3172038

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:34:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 16:11:44

US3172038

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 14:20:00

US3172038

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
User entered '18 Aug 2020'	Mariete Rendon (b) (4)	20 Aug 2020 14:20:00
	(b) (4)	

US3172038

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered 'Contact Made (CONTACT MADE)'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 14:20:00

US3172038

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered empty.	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 14:20:00

US3172038

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 14:20:09

US3172038

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User entered 'I'	System	20 Aug 2020 14:20:09

US3172038

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:41:46

US3172038

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
User entered '26 Aug 2020'	Mariete Rendon (b) (4)	26 Aug 2020 18:41:46
	(b) (4)	

US3172038

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Mariete Rendon (b) (4)	26 Aug 2020 18:41:46
	(b) (4)	

US3172038

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered empty.	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:41:46

US3172038

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 18:42:49

US3172038

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User entered 'I'	System	26 Aug 2020 18:42:49

US3172038

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	16 Sep 2020 19:05:19

US3172038

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
User entered '02 Sep 2020'	Jessie Downs (b) (4)	16 Sep 2020 19:05:19
	(b) (4)	

US3172038

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered 'Contact Not Made (CONTACT NOT MADE)'	Jessie Downs (b) (4) (b) (4)	16 Sep 2020 19:05:19

US3172038

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered 'Unable to contact subject. Left message to call site back.'	Jessie Downs (b) (4) (b) (4)	16 Sep 2020 19:05:19

US3172038

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	16 Sep 2020 19:05:31

US3172038

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User entered 'I'	System	16 Sep 2020 19:05:31

US3172038

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:34:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	30 Sep 2020 20:02:21

US3172038

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered empty.	Jessie Downs (b) (4) (b) (4)	30 Sep 2020 20:02:21

US3172038

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:34:29

[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 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered empty.	Jessie Downs (b) (4) (b) (4)	30 Sep 2020 20:02:21

US3172038

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:34:29

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User entered 'VISIT2'	System	30 Sep 2020 20:02:21

US3172038

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:29

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User accepted default value 'Pre-Dose (PREDOSE)'	Jessie Downs (b) (4) (b) (4)	30 Sep 2020 20:02:28

US3172038

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	30 Sep 2020 20:02:28

US3172038

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered empty.	Jessie Downs (b) (4) (b) (4)	30 Sep 2020 20:02:28

US3172038

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered empty.	Jessie Downs (b) (4) (b) (4)	30 Sep 2020 20:02:28

US3172038

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User entered empty.	System	30 Sep 2020 20:02:28

US3172038

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered empty.	Jessie Downs (b) (4) (b) (4)	30 Sep 2020 20:02:28

US3172038

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered empty.	Jessie Downs (b) (4) (b) (4)	30 Sep 2020 20:02:28

US3172038

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered empty.	Jessie Downs (b) (4) (b) (4)	30 Sep 2020 20:02:28

US3172038

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered empty.	Jessie Downs (b) (4) (b) (4)	30 Sep 2020 20:02:28

US3172038

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User entered empty.	System	30 Sep 2020 20:02:28

US3172038

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered empty.	Jessie Downs (b) (4) (b) (4)	30 Sep 2020 20:02:28

US3172038

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User entered empty.	System	30 Sep 2020 20:02:28

US3172038

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered empty.	Jessie Downs (b) (4) (b) (4)	30 Sep 2020 20:02:28

US3172038

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User entered empty.	System	30 Sep 2020 20:02:28

US3172038

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered empty.	Jessie Downs (b) (4) (b) (4)	30 Sep 2020 20:02:28

US3172038

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:29

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User entered empty.	System	30 Sep 2020 20:02:28

US3172038

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:29

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User accepted default value 'Post-Dose (POSTDOSE)'	Jessie Downs (b) (4) (b) (4)	30 Sep 2020 20:02:28

US3172038

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	30 Sep 2020 20:02:28

US3172038

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered empty.	Jessie Downs (b) (4) (b) (4)	30 Sep 2020 20:02:28

US3172038

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered empty.	Jessie Downs (b) (4) (b) (4)	30 Sep 2020 20:02:28

US3172038

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User entered empty.	System	30 Sep 2020 20:02:28

US3172038

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered empty.	Jessie Downs (b) (4) (b) (4)	30 Sep 2020 20:02:28

US3172038

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered empty.	Jessie Downs (b) (4) (b) (4)	30 Sep 2020 20:02:28

US3172038

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered empty.	Jessie Downs (b) (4) (b) (4)	30 Sep 2020 20:02:28

US3172038

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered empty.	Jessie Downs (b) (4) (b) (4)	30 Sep 2020 20:02:28

US3172038

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User entered empty.	System	30 Sep 2020 20:02:28

US3172038

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered empty.	Jessie Downs (b) (4) (b) (4)	30 Sep 2020 20:02:28

US3172038

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User entered empty.	System	30 Sep 2020 20:02:28

US3172038

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered empty.	Jessie Downs (b) (4) (b) (4)	30 Sep 2020 20:02:28

US3172038

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User entered empty.	System	30 Sep 2020 20:02:28

US3172038

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered empty.	Jessie Downs (b) (4) (b) (4)	30 Sep 2020 20:02:28

US3172038

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:29

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User entered empty.	System	30 Sep 2020 20:02:28

US3172038

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:34:29

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	30 Sep 2020 20:02:32

US3172038

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:34:29

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered empty.	Jessie Downs (b) (4) (b) (4)	30 Sep 2020 20:02:32

US3172038

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:34:29

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	30 Sep 2020 20:02:38

US3172038

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:34:29

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User closed query 'Was study treatment given? is No, System however If No, reason not given is not provided. Please review and reconcile.' (Site from System).		30 Sep 2020 20:02:48
User entered 'Other (OTHER)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	30 Sep 2020 20:02:48
User opened query 'Was study treatment given? is No, however If No, reason not given is not provided. Please review and reconcile.' (Site from System).	System	30 Sep 2020 20:02:38
User entered empty.	Jessie Downs (b) (4) (b) (4)	30 Sep 2020 20:02:38

US3172038

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:34:29

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 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered 'SAE' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	13 Nov 2020 17:56:23
User closed query 'Per CDM: If the subject missed the visit please update the Dosing discontinuation form under the End of study folder else clarify. thank you. ' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 15:20:49
Query 'Per CDM: If the subject missed the visit please update the Dosing discontinuation form under the End of study folder else clarify. thank you. ' answered with 'Dosing discontinuation page has been updated.' (Site from DM).	Mariete Rendon (b) (4) (b) (4)	08 Oct 2020 17:40:15
User opened query 'Per CDM: If the subject missed the visit please update the Dosing discontinuation form under the End of study folder else clarify. thank you. ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 03:24:34
User entered 'Missed Visit' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	30 Sep 2020 20:02:48
User entered empty.	Jessie Downs (b) (4) (b) (4)	30 Sep 2020 20:02:38

US3172038

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:34:29

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User entered empty.	System	30 Sep 2020 20:02:38

US3172038

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:34:29

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered empty.	Jessie Downs (b) (4) (b) (4)	30 Sep 2020 20:02:38

US3172038

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered empty.	Jessie Downs (b) (4) (b) (4)	30 Sep 2020 20:02:38

US3172038

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User entered empty.	System	30 Sep 2020 20:02:38

US3172038

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered empty.	Jessie Downs (b) (4) (b) (4)	30 Sep 2020 20:02:38

US3172038

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User entered empty.	System	30 Sep 2020 20:02:38

US3172038

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:34:29

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User entered empty.	System	30 Sep 2020 20:02:38

US3172038

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:34:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	30 Sep 2020 20:02:54

US3172038

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:34:29

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered empty.	Jessie Downs (b) (4) (b) (4)	30 Sep 2020 20:02:54

US3172038

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:34:29

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered empty.	Jessie Downs (b) (4) (b) (4)	30 Sep 2020 20:02:54

US3172038

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User entered empty.	System	30 Sep 2020 20:02:54

US3172038

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:34:29

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered empty.	Jessie Downs (b) (4) (b) (4)	30 Sep 2020 20:02:59

US3172038

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:34:29

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Jessie Downs (b) (4) (b) (4)	30 Sep 2020 20:02:59

US3172038

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:34:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	30 Sep 2020 20:02:59

US3172038

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:34:29

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered empty.	Jessie Downs (b) (4) (b) (4)	30 Sep 2020 20:02:59

US3172038

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User entered empty.	System	30 Sep 2020 20:02:59

US3172038

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:34:29

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Jessie Downs (b) (4) (b) (4)	30 Sep 2020 20:02:59

US3172038

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:34:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	30 Sep 2020 20:02:59

US3172038

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:34:29

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered empty.	Jessie Downs (b) (4) (b) (4)	30 Sep 2020 20:02:59

US3172038

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User entered empty.	System	30 Sep 2020 20:02:59

US3172038

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	29 Sep 2020 19:55:00

US3172038

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User entered '1'	System	29 Sep 2020 19:55:00

US3172038

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	29 Sep 2020 19:55:23

US3172038

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:29

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User closed query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	04 Dec 2020 21:08:41
User opened query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	04 Dec 2020 20:55:19
User entered '15 Sep 2020'	Jessie Downs (b) (4) (b) (4)	29 Sep 2020 19:55:23

US3172038

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	29 Sep 2020 19:55:23

US3172038

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered empty.	Jessie Downs (b) (4) (b) (4)	29 Sep 2020 19:55:23

US3172038

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	29 Sep 2020 19:55:41

US3172038

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User entered 'I'	System	29 Sep 2020 19:55:41

US3172038

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	29 Sep 2020 20:00:50

US3172038

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:29

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User closed query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	04 Dec 2020 21:08:41
User opened query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	04 Dec 2020 20:55:19
User entered '24 Sep 2020'	Jessie Downs (b) (4) (b) (4)	29 Sep 2020 20:00:50

US3172038

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered 'Contact Not Made (CONTACT NOT MADE)'	Jessie Downs (b) (4) (b) (4)	29 Sep 2020 20:00:50

US3172038

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered 'Subject could not be reached. Contacted emergency contact and they mentioned subject is again hospitalized for the same issue (acute pyelonephritis, not resolved)'	Jessie Downs (b) (4) (b) (4)	29 Sep 2020 20:00:50

US3172038

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	08 Feb 2021 16:59:01
User entered 'No (N)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	07 Oct 2020 19:35:14
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	29 Sep 2020 20:01:40

US3172038

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User entered '1'	System	08 Feb 2021 16:59:01
User entered empty.	System	07 Oct 2020 19:35:14
User entered '1'	System	29 Sep 2020 20:01:40

US3172038

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:49:04
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	26 Feb 2021 21:45:22

US3172038

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:49:04
User entered empty.	Mariete Rendon (b) (4) (b) (4)	26 Feb 2021 21:45:22

US3172038

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:49:04
User entered empty.	Mariete Rendon (b) (4) (b) (4)	26 Feb 2021 21:45:22

US3172038

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:49:04
User entered 'Not done'	Mariete Rendon (b) (4) (b) (4)	26 Feb 2021 21:45:22

US3172038

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	08 Feb 2021 16:59:12

US3172038

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User entered 'I'	System	08 Feb 2021 16:59:12

US3172038

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:34:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	23 Feb 2021 14:34:14
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	19 Feb 2021 19:46:53

US3172038

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	23 Feb 2021 14:34:14
User entered empty.	Jessie Downs (b) (4) (b) (4)	19 Feb 2021 19:46:53

US3172038

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:34:29

[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 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	23 Feb 2021 14:34:14
User entered empty.	Jessie Downs (b) (4) (b) (4)	19 Feb 2021 19:46:53

US3172038

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:34:29

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User entered 'VISIT3'	System	19 Feb 2021 19:46:53

US3172038

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	23 Feb 2021 14:34:14
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	19 Feb 2021 19:46:47

US3172038

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	23 Feb 2021 14:34:14
User entered empty.	Jessie Downs (b) (4) (b) (4)	19 Feb 2021 19:46:47

US3172038

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	23 Feb 2021 14:34:14
User entered empty.	Jessie Downs (b) (4) (b) (4)	19 Feb 2021 19:46:47

US3172038

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:58
User entered empty.	System	19 Feb 2021 19:46:47

US3172038

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	23 Feb 2021 14:34:14
User entered empty.	Jessie Downs (b) (4) (b) (4)	19 Feb 2021 19:46:47

US3172038

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	23 Feb 2021 14:34:14
User entered empty.	Jessie Downs (b) (4) (b) (4)	19 Feb 2021 19:46:47

US3172038

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	23 Feb 2021 14:34:14
User entered empty.	Jessie Downs (b) (4) (b) (4)	19 Feb 2021 19:46:47

US3172038

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	23 Feb 2021 14:34:14
User entered empty.	Jessie Downs (b) (4) (b) (4)	19 Feb 2021 19:46:47

US3172038

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:58
User entered empty.	System	19 Feb 2021 19:46:47

US3172038

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	23 Feb 2021 14:34:14
User entered empty.	Jessie Downs (b) (4) (b) (4)	19 Feb 2021 19:46:47

US3172038

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:58
User entered empty.	System	19 Feb 2021 19:46:47

US3172038

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	23 Feb 2021 14:34:14
User entered empty.	Jessie Downs (b) (4) (b) (4)	19 Feb 2021 19:46:47

US3172038

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:58
User entered empty.	System	19 Feb 2021 19:46:47

US3172038

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	23 Feb 2021 14:34:14
User entered empty.	Jessie Downs (b) (4) (b) (4)	19 Feb 2021 19:46:47

US3172038

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:29

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:58
User entered empty.	System	19 Feb 2021 19:46:47

US3172038

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:29

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:58

US3172038

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:29

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:58

US3172038

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:34:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	23 Feb 2021 14:34:14
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	19 Feb 2021 19:46:40

US3172038

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:34:29

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	23 Feb 2021 14:34:14
User entered empty.	Jessie Downs (b) (4) (b) (4)	19 Feb 2021 19:46:40

US3172038

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:34:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	23 Feb 2021 14:34:14
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	19 Feb 2021 19:20:51

US3172038

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:34:29

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	23 Feb 2021 14:34:14
User entered empty.	Jessie Downs (b) (4) (b) (4)	19 Feb 2021 19:20:51

US3172038

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:34:29

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	23 Feb 2021 14:34:14
User entered empty.	Jessie Downs (b) (4) (b) (4)	19 Feb 2021 19:20:51

US3172038

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User entered empty.	System	19 Feb 2021 19:20:51

US3172038

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	08 Feb 2021 16:59:24

US3172038

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User entered '1'	System	08 Feb 2021 16:59:24

US3172038

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
Data entry locked.	System	11 Aug 2020 16:11:44
User entered 'Day 64'	System	11 Aug 2020 16:11:44

US3172038

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-10-11T00:21:59', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '87433081-e52d-4a66-a4b6-b2ad17861051'	System	11 Oct 2020 04:22:28
User entered 'Yes (Y)'	System	11 Oct 2020 04:22:28

US3172038

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-10-11T00:21:55', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '87433081-e52d-4a66-a4b6-b2ad17861051'	System	11 Oct 2020 04:22:28
User entered 'No (N)'	System	11 Oct 2020 04:22:28

US3172038

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-10-11T00:22:06', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '87433081-e52d-4a66-a4b6-b2ad17861051'	System	11 Oct 2020 04:22:28
User entered 'No (N)'	System	11 Oct 2020 04:22:28

US3172038

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-10-11T00:22:12', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '87433081-e52d-4a66-a4b6-b2ad17861051'	System	11 Oct 2020 04:22:28
User entered 'Yes (Y)'	System	11 Oct 2020 04:22:28

US3172038

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-10-11T00:22:15', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '87433081-e52d-4a66-a4b6-b2ad17861051'	System	11 Oct 2020 04:22:28
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	11 Oct 2020 04:22:28

US3172038

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-10-11T00:22:18', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '87433081-e52d-4a66-a4b6-b2ad17861051' User entered '11 Oct 2020 00:22:18'	System	11 Oct 2020 04:22:28
	System	11 Oct 2020 04:22:28

US3172038

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
Data entry locked.	System	11 Aug 2020 16:11:44
User entered '11 Oct 2020 00:01'	System	11 Aug 2020 16:11:44

US3172038

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
Data entry locked.	System	11 Aug 2020 16:11:44
User entered '15 Oct 2020 23:59'	System	11 Aug 2020 16:11:44

US3172038

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
Data entry locked.	System	11 Aug 2020 16:11:44
User entered 'Day 71'	System	11 Aug 2020 16:11:44

US3172038

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-10-18T22:44:02', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: 'fbd58780-e25d-4583-9320-a2966919827a' User entered 'No (N)'	System	19 Oct 2020 02:44:12
	System	19 Oct 2020 02:44:12

US3172038

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-10-18T22:44:07', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: 'fbd58780-e25d-4583-9320-a2966919827a' User entered 'No (N)'	System	19 Oct 2020 02:44:12
	System	19 Oct 2020 02:44:12

US3172038

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-10-18T22:44:10', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: 'fbd58780-e25d-4583-9320-a2966919827a' User entered '18 Oct 2020 22:44:10'	System	19 Oct 2020 02:44:12
	System	19 Oct 2020 02:44:12

US3172038

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
Data entry locked.	System	11 Aug 2020 16:11:44
User entered '18 Oct 2020 00:01'	System	11 Aug 2020 16:11:44

US3172038

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
Data entry locked.	System	11 Aug 2020 16:11:44
User entered '22 Oct 2020 23:59'	System	11 Aug 2020 16:11:44

US3172038

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
Data entry locked.	System	11 Aug 2020 16:11:44
User entered 'Day 78'	System	11 Aug 2020 16:11:44

US3172038

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-10-25T05:56:25', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '38e963bd-0a9b-4a1b-a929-acfe8914642d' User entered 'No (N)'	System	25 Oct 2020 09:56:35
	System	25 Oct 2020 09:56:35

US3172038

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEE6D59)', Time: '2020-10-25T05:56:29', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '38e963bd-0a9b-4a1b-a929-acfe8914642d' User entered 'No (N)'	System	25 Oct 2020 09:56:35
	System	25 Oct 2020 09:56:35

US3172038

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-10-25T05:56:32', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '38e963bd-0a9b-4a1b-a929-acfe8914642d' User entered '25 Oct 2020 05:56:32'	System	25 Oct 2020 09:56:35
	System	25 Oct 2020 09:56:35

US3172038

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
Data entry locked.	System	11 Aug 2020 16:11:44
User entered '25 Oct 2020 00:01'	System	11 Aug 2020 16:11:44

US3172038

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
Data entry locked.	System	11 Aug 2020 16:11:44
User entered '29 Oct 2020 23:59'	System	11 Aug 2020 16:11:44

US3172038

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
Data entry locked.	System	11 Aug 2020 16:11:44
User entered 'Day 92'	System	11 Aug 2020 16:11:44

US3172038

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-11-08T13:44:59', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: 'c5309a76-304d-459f-b8c8-e75a1c13f1c7' User entered 'No (N)'	System	08 Nov 2020 18:45:11
	System	08 Nov 2020 18:45:11

US3172038

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-11-08T13:45:03', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: 'c5309a76-304d-459f-b8c8-e75a1c13f1c7'	System	08 Nov 2020 18:45:11
User entered 'No (N)'	System	08 Nov 2020 18:45:11

US3172038

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-11-08T13:45:06', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: 'c5309a76-304d-459f-b8c8-e75a1c13f1c7' User entered '08 Nov 2020 13:45:06'	System	08 Nov 2020 18:45:11
	System	08 Nov 2020 18:45:11

US3172038

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
Data entry locked.	System	11 Aug 2020 16:11:44
User entered '08 Nov 2020 00:01'	System	11 Aug 2020 16:11:44

US3172038

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:56:58
Data entry locked.	System	11 Aug 2020 16:11:44
User entered '12 Nov 2020 23:59'	System	11 Aug 2020 16:11:44

US3172038

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:28:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:40:57
Data entry locked.	System	11 Aug 2020 16:11:44
User entered 'Day 99'	System	11 Aug 2020 16:11:44

US3172038

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:28:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:40:57

US3172038

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:28:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:40:57

US3172038

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:28:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:40:57

US3172038

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:28:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:40:57

US3172038

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:28:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:40:57

US3172038

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:28:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:40:57

US3172038

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:28:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:40:57

US3172038

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:28:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:40:57

US3172038

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:28:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:40:57

US3172038

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:28:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:40:57

US3172038

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:28:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:40:57

US3172038

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:28:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:40:57

US3172038

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:28:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:40:57

US3172038

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:28:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:40:57

US3172038

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:28:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:40:57

US3172038

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:28:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:40:57

US3172038

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:28:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:40:57

US3172038

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:28:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:40:57

US3172038

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:28:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:40:57

US3172038

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:28:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:40:57

US3172038

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:28:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:40:57

US3172038

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:28:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:40:57

US3172038

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:28:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:40:57

US3172038

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:28:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:40:57

US3172038

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:28:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:40:57

US3172038

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:28:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:40:57
Data entry locked.	System	11 Aug 2020 16:11:44
User entered '15 Nov 2020 00:01'	System	11 Aug 2020 16:11:44

US3172038

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:28:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:40:57
Data entry locked.	System	11 Aug 2020 16:11:44
User entered '19 Nov 2020 23:59'	System	11 Aug 2020 16:11:44

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Have you been exposed to someone with 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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Have you been exposed to someone with 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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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 (AFFCC927-4E0C-4992-BF2F-A2C8FEEE6D59)', Time: '2020-12-05T05:42:19', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '7bb12a30-d681-487c-9ac8-a7ac79d47b62'	System	05 Dec 2020 10:42:33
User entered 'No (N)'	System	05 Dec 2020 10:42:33
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Have you been exposed to someone with 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 (AFFCC927-4E0C-4992-BF2F-A2C8FEEE6D59)', Time: '2020-12-05T05:42:25', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '7bb12a30-d681-487c-9ac8-a7ac79d47b62'	System	05 Dec 2020 10:42:33
User entered 'No (N)'	System	05 Dec 2020 10:42:33
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-12-05T05:42:29', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '7bb12a30-d681-487c-9ac8-a7ac79d47b62'	System	05 Dec 2020 10:42:33
User entered '05 Dec 2020 05:42:29'	System	05 Dec 2020 10:42:33
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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 (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-12-10T07:47:35', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '2e6387e9-ab34-40b6-8f97-e36bedad19aa'	System	10 Dec 2020 12:47:44
User entered 'No (N)'	System	10 Dec 2020 12:47:44
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Have you been exposed to someone with 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 (AFFCC927-4E0C-4992-BF2F-A2C8FEEE6D59)', Time: '2020-12-10T07:47:39', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '2e6387e9-ab34-40b6-8f97-e36bedad19aa'	System	10 Dec 2020 12:47:44
User entered 'No (N)'	System	10 Dec 2020 12:47:44
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFFCC927-4E0C-4992-BF2F-A2C8FEEEE6D59)', Time: '2020-12-10T07:47:42', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '2e6387e9-ab34-40b6-8f97-e36bedad19aa'	System	10 Dec 2020 12:47:44
User entered '10 Dec 2020 07:47:42'	System	10 Dec 2020 12:47:44
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Have you been exposed to someone with 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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
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US3172038

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Have you been exposed to someone with 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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
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US3172038

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Have you been exposed to someone with 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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
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US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Have you been exposed to someone with 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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Have you been exposed to someone with 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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
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US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

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Folder: New Safety Follow Up Diary (1)

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Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 03:40:57

US3172038

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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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Have you been exposed to someone with 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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

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US3172038

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Have you been exposed to someone with 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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
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US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Have you been exposed to someone with 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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 15:34:29

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
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US3172038

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
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Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
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Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Have you been exposed to someone with 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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

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Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Have you been exposed to someone with 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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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 (53AC63F5-C23E-4645-8450-2B29D92397F9)', Time: '2021-03-01T13:21:05-05:00', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '70413f04-9ac8-4db4-ba2e-85cb1b3577d7'	System	01 Mar 2021 18:24:45
User entered 'No (N)'	System	01 Mar 2021 18:24:45
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Have you been exposed to someone with 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 (53AC63F5-C23E-4645-8450-2B29D92397F9)', Time: '2021-03-01T13:21:02-05:00', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '70413f04-9ac8-4db4-ba2e-85cb1b3577d7'	System	01 Mar 2021 18:24:45
User entered 'No (N)'	System	01 Mar 2021 18:24:45
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53AC63F5-C23E-4645-8450-2B29D92397F9)', Time: '2021-03-01T13:21:09-05:00', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '70413f04-9ac8-4db4-ba2e-85cb1b3577d7'	System	01 Mar 2021 18:24:45
User entered '01 Mar 2021 13:21:09'	System	01 Mar 2021 18:24:45
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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 (53AC63F5-C23E-4645-8450-2B29D92397F9)', Time: '2021-03-04T03:18:45-05:00', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: 'ce4c1332-a1ef-4b68-9af9-20e082312588'	System	04 Mar 2021 08:18:53
User entered 'No (N)'	System	04 Mar 2021 08:18:53
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Have you been exposed to someone with 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 (53AC63F5-C23E-4645-8450-2B29D92397F9)', Time: '2021-03-04T03:18:48-05:00', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: 'ce4c1332-a1ef-4b68-9af9-20e082312588'	System	04 Mar 2021 08:18:53
User entered 'No (N)'	System	04 Mar 2021 08:18:53
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53AC63F5-C23E-4645-8450-2B29D92397F9)', Time: '2021-03-04T03:18:51-05:00', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: 'ce4c1332-a1ef-4b68-9af9-20e082312588'	System	04 Mar 2021 08:18:53
User entered '04 Mar 2021 03:18:51'	System	04 Mar 2021 08:18:53
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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 (53AC63F5-C23E-4645-8450-2B29D92397F9)', Time: '2021-03-11T17:30:35-05:00', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: 'dce3c768-c4d3-4156-b19c-510870e3b283'	System	11 Mar 2021 22:30:44
User entered 'No (N)'	System	11 Mar 2021 22:30:44
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Have you been exposed to someone with 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 (53AC63F5-C23E-4645-8450-2B29D92397F9)', Time: '2021-03-11T17:30:38-05:00', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: 'dce3c768-c4d3-4156-b19c-510870e3b283'	System	11 Mar 2021 22:30:44
User entered 'No (N)'	System	11 Mar 2021 22:30:44
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53AC63F5-C23E-4645-8450-2B29D92397F9)', Time: '2021-03-11T17:30:40-05:00', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: 'dce3c768-c4d3-4156-b19c-510870e3b283'	System	11 Mar 2021 22:30:44
User entered '11 Mar 2021 17:30:40'	System	11 Mar 2021 22:30:44
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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 (53AC63F5-C23E-4645-8450-2B29D92397F9)', Time: '2021-03-18T06:00:20-04:00', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: 'ca4a23c9-f163-498e-a391-cdfd296b3369'	System	18 Mar 2021 10:00:29
User entered 'No (N)'	System	18 Mar 2021 10:00:29
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Have you been exposed to someone with 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 (53AC63F5-C23E-4645-8450-2B29D92397F9)', Time: '2021-03-18T06:00:23-04:00', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: 'ca4a23c9-f163-498e-a391-cdfd296b3369'	System	18 Mar 2021 10:00:29
User entered 'No (N)'	System	18 Mar 2021 10:00:29
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53AC63F5-C23E-4645-8450-2B29D92397F9)', Time: '2021-03-18T06:00:26-04:00', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: 'ca4a23c9-f163-498e-a391-cdfd296b3369'	System	18 Mar 2021 10:00:29
User entered '18 Mar 2021 06:00:26'	System	18 Mar 2021 10:00:29
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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 (53AC63F5-C23E-4645-8450-2B29D92397F9)', Time: '2021-03-25T17:50:30-05:00', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '232e11ea-15b5-48dc-a071-bb5f3e716560'	System	25 Mar 2021 22:50:43
User entered 'No (N)'	System	25 Mar 2021 22:50:43
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Have you been exposed to someone with 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 (53AC63F5-C23E-4645-8450-2B29D92397F9)', Time: '2021-03-25T17:50:32-05:00', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '232e11ea-15b5-48dc-a071-bb5f3e716560'	System	25 Mar 2021 22:50:43
User entered 'No (N)'	System	25 Mar 2021 22:50:43
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53AC63F5-C23E-4645-8450-2B29D92397F9)', Time: '2021-03-25T17:50:35-05:00', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '232e11ea-15b5-48dc-a071-bb5f3e716560'	System	25 Mar 2021 22:50:43
User entered '25 Mar 2021 17:50:35'	System	25 Mar 2021 22:50:43
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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 (53AC63F5-C23E-4645-8450-2B29D92397F9)', Time: '2021-04-01T04:29:20-04:00', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '1e20f287-401e-4ec9-a704-2bbf1b02f317'	System	01 Apr 2021 08:29:27
User entered 'No (N)'	System	01 Apr 2021 08:29:27
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Have you been exposed to someone with 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 (53AC63F5-C23E-4645-8450-2B29D92397F9)', Time: '2021-04-01T04:29:22-04:00', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '1e20f287-401e-4ec9-a704-2bbf1b02f317'	System	01 Apr 2021 08:29:27
User entered 'No (N)'	System	01 Apr 2021 08:29:27
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53AC63F5-C23E-4645-8450-2B29D92397F9)', Time: '2021-04-01T04:29:25-04:00', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '1e20f287-401e-4ec9-a704-2bbf1b02f317'	System	01 Apr 2021 08:29:27
User entered '01 Apr 2021 04:29:25'	System	01 Apr 2021 08:29:27
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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 (53AC63F5-C23E-4645-8450-2B29D92397F9)', Time: '2021-04-08T05:19:47-04:00', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: 'e395fd2d-8fe9-46b0-863f-956e5bfada2d'	System	08 Apr 2021 09:20:05
User entered 'No (N)'	System	08 Apr 2021 09:20:05
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Have you been exposed to someone with 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 (53AC63F5-C23E-4645-8450-2B29D92397F9)', Time: '2021-04-08T05:19:58-04:00', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: 'e395fd2d-8fe9-46b0-863f-956e5bfada2d'	System	08 Apr 2021 09:20:05
User entered 'No (N)'	System	08 Apr 2021 09:20:05
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53AC63F5-C23E-4645-8450-2B29D92397F9)', Time: '2021-04-08T05:20:01-04:00', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: 'e395fd2d-8fe9-46b0-863f-956e5bfada2d'	System	08 Apr 2021 09:20:05
User entered '08 Apr 2021 05:20:01'	System	08 Apr 2021 09:20:05
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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 (53AC63F5-C23E-4645-8450-2B29D92397F9)', Time: '2021-04-15T07:24:51-04:00', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '9912973e-a565-4459-9741-e4ceb652128c'	System	15 Apr 2021 11:25:15
User entered 'No (N)'	System	15 Apr 2021 11:25:15
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Have you been exposed to someone with 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 (53AC63F5-C23E-4645-8450-2B29D92397F9)', Time: '2021-04-15T07:25:10-04:00', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '9912973e-a565-4459-9741-e4ceb652128c'	System	15 Apr 2021 11:25:15
User entered 'No (N)'	System	15 Apr 2021 11:25:15
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53AC63F5-C23E-4645-8450-2B29D92397F9)', Time: '2021-04-15T07:25:12-04:00', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '9912973e-a565-4459-9741-e4ceb652128c'	System	15 Apr 2021 11:25:15
User entered '15 Apr 2021 07:25:12'	System	15 Apr 2021 11:25:15
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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 (53AC63F5-C23E-4645-8450-2B29D92397F9)', Time: '2021-04-22T00:02:13-04:00', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '52fbdb6a-d1c4-4be9-8bf8-82e11ad8b396'	System	22 Apr 2021 04:02:53
User entered 'No (N)'	System	22 Apr 2021 04:02:53
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 15:34:29

Have you been exposed to someone with 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 (53AC63F5-C23E-4645-8450-2B29D92397F9)', Time: '2021-04-22T00:02:18-04:00', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '52fbdb6a-d1c4-4be9-8bf8-82e11ad8b396'	System	22 Apr 2021 04:02:53
User entered 'No (N)'	System	22 Apr 2021 04:02:53
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53AC63F5-C23E-4645-8450-2B29D92397F9)', Time: '2021-04-22T00:02:21-04:00', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '52fbdb6a-d1c4-4be9-8bf8-82e11ad8b396'	System	22 Apr 2021 04:02:53
User entered '22 Apr 2021 00:02:21'	System	22 Apr 2021 04:02:53
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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 (53AC63F5-C23E-4645-8450-2B29D92397F9)', Time: '2021-04-29T05:19:06-04:00', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: 'f320e89a-4d38-47ce-ab36-9ffaf0467fe'	System	03 May 2021 12:03:35
User entered 'No (N)'	System	03 May 2021 12:03:35
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Have you been exposed to someone with 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 (53AC63F5-C23E-4645-8450-2B29D92397F9)', Time: '2021-04-29T05:19:12-04:00', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: 'f320e89a-4d38-47ce-ab36-9ffaf0467fe'	System	03 May 2021 12:03:35
User entered 'No (N)'	System	03 May 2021 12:03:35
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53AC63F5-C23E-4645-8450-2B29D92397F9)', Time: '2021-04-29T05:19:14-04:00', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: 'f320e89a-4d38-47ce-ab36-9ffaf0467fe'	System	03 May 2021 12:03:35
User entered '29 Apr 2021 05:19:14'	System	03 May 2021 12:03:35
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Have you been exposed to someone with 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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Have you been exposed to someone with 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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Have you been exposed to someone with 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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
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US3172038

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Have you been exposed to someone with 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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
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US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
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US3172038

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
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US3172038

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Have you been exposed to someone with 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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
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US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

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DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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)
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DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Have you been exposed to someone with 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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 03:40:57

US3172038

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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Have you been exposed to someone with 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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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

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US3172038

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 15:34:29

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

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Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
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US3172038

Folder: New Safety Follow Up Diary (1)

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Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 03:40:57

US3172038

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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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Have you been exposed to someone with 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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

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US3172038

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 15:34:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Have you been exposed to someone with 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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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US3172038

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

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US3172038

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Have you been exposed to someone with 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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
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Folder: New Safety Follow Up Diary (1)

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Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

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Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Have you been exposed to someone with 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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
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US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Have you been exposed to someone with 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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
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US3172038

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
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US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Have you been exposed to someone with 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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
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US3172038

Folder: New Safety Follow Up Diary (1)

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

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[Date and time of submission](#)

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US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Have you been exposed to someone with 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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Have you been exposed to someone with 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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
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US3172038

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 15:34:29

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
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US3172038

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
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US3172038

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Have you been exposed to someone with 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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 15:34:29

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Have you been exposed to someone with 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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

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US3172038

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Have you been exposed to someone with 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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

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Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
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Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

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DataPoint Activated.	System	04 Dec 2020 21:08:41
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Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Have you been exposed to someone with 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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
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US3172038

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Have you been exposed to someone with 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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
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US3172038

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
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US3172038

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
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US3172038

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Have you been exposed to someone with 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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
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[Date and time of submission](#)

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DataPoint Activated.	System	04 Dec 2020 21:08:41
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US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 03:40:57

US3172038

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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Have you been exposed to someone with 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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Have you been exposed to someone with 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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Have you been exposed to someone with 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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Have you been exposed to someone with 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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
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DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

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US3172038

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Have you been exposed to someone with 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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

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Folder: New Safety Follow Up Diary (1)

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DataPoint Activated.	System	04 Dec 2020 21:08:41
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DataPoint Activated.	System	04 Dec 2020 21:08:41
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US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Have you been exposed to someone with 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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Have you been exposed to someone with 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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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US3172038

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

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US3172038

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Have you been exposed to someone with 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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
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US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
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Folder: New Safety Follow Up Diary (1)

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Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

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DataPoint Activated.	System	04 Dec 2020 21:08:41
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US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Have you been exposed to someone with 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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Have you been exposed to someone with 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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Have you been exposed to someone with 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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Have you been exposed to someone with 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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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DataPoint Activated.	System	04 Dec 2020 21:08:41
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[Date and time of submission](#)

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US3172038

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Have you been exposed to someone with 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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
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Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

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US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Have you been exposed to someone with 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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Have you been exposed to someone with 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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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

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US3172038

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

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US3172038

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Have you been exposed to someone with 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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
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Folder: New Safety Follow Up Diary (1)

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

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Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
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US3172038

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Have you been exposed to someone with 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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
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US3172038

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[Date and time of submission](#)

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US3172038

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Have you been exposed to someone with 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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
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US3172038

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
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US3172038

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
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US3172038

Folder: New Safety Follow Up Diary (1)

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Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
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US3172038

Folder: New Safety Follow Up Diary (1)

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[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
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US3172038

Folder: New Safety Follow Up Diary (1)

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Audit	User	Time (GMT)
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US3172038

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
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US3172038

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Have you been exposed to someone with 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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
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US3172038

Folder: New Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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US3172038

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
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US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 03:40:57

US3172038

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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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)
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DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

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DataPoint Activated.	System	04 Dec 2020 21:08:41
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US3172038

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US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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

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DataPoint Activated.	System	04 Dec 2020 21:08:41
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US3172038

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

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TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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)
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US3172038

Folder: New Safety Follow Up Diary (1)

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

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

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US3172038

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Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

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Folder: New Safety Follow Up Diary (1)

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[New loss of smell](#)

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DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

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[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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[Congestion](#)

Audit	User	Time (GMT)
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DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

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[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

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TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[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)
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DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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Have you been exposed to someone with 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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

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US3172038

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
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US3172038

Folder: New Safety Follow Up Diary (1)

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Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Have you been exposed to someone with 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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Have you been exposed to someone with 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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Have you been exposed to someone with 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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
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US3172038

Folder: New Safety Follow Up Diary (1)

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US3172038

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
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US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Have you been exposed to someone with 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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

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US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
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US3172038

Folder: New Safety Follow Up Diary (1)

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US3172038

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[Date and time of submission](#)

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US3172038

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
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US3172038

Folder: New Safety Follow Up Diary (1)

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Have you been exposed to someone with 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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
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US3172038

Folder: New Safety Follow Up Diary (1)

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DataPoint Activated.	System	04 Dec 2020 21:08:41
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US3172038

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
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US3172038

Folder: New Safety Follow Up Diary (1)

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
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US3172038

Folder: New Safety Follow Up Diary (1)

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[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
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US3172038

Folder: New Safety Follow Up Diary (1)

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[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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

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US3172038

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Have you been exposed to someone with 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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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US3172038

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[Date and time of submission](#)

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US3172038

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Have you been exposed to someone with 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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
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US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
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Folder: New Safety Follow Up Diary (1)

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US3172038

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 03:40:57

US3172038

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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Have you been exposed to someone with 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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
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US3172038

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Have you been exposed to someone with 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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

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DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Have you been exposed to someone with 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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

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Folder: New Safety Follow Up Diary (1)

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Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
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US3172038

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Have you been exposed to someone with 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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
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US3172038

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Have you been exposed to someone with 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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
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US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
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US3172038

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
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US3172038

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Have you been exposed to someone with 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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
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US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
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US3172038

Folder: New Safety Follow Up Diary (1)

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

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Folder: New Safety Follow Up Diary (1)

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DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Have you been exposed to someone with 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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Have you been exposed to someone with 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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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DataPoint Activated.	System	04 Dec 2020 21:08:41
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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
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US3172038

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Have you been exposed to someone with 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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Have you been exposed to someone with 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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 15:34:29

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Have you been exposed to someone with 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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
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US3172038

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Have you been exposed to someone with 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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 15:34:29

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Have you been exposed to someone with 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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Have you been exposed to someone with 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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
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US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
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US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
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US3172038

Folder: New Safety Follow Up Diary (1)

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US3172038

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[Date and time of submission](#)

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DataPoint Activated.	System	04 Dec 2020 21:08:41
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US3172038

Folder: New Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Have you been exposed to someone with 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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Have you been exposed to someone with 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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
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US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
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US3172038

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Have you been exposed to someone with 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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Have you been exposed to someone with 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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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US3172038

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

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US3172038

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Have you been exposed to someone with 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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
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Folder: New Safety Follow Up Diary (1)

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Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
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US3172038

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
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US3172038

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Have you been exposed to someone with 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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
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US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Have you been exposed to someone with 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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
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US3172038

Folder: New Safety Follow Up Diary (1)

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Audit	User	Time (GMT)
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US3172038

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
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US3172038

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Have you been exposed to someone with 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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
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US3172038

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
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[Date and time of submission](#)

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US3172038

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Have you been exposed to someone with 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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Have you been exposed to someone with 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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Have you been exposed to someone with 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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Have you been exposed to someone with 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)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '13 Oct 2022 00:01'	System	19 Nov 2020 03:40:57

US3172038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	04 Dec 2020 21:08:41
DataPoint Inactivated.	System	04 Dec 2020 20:55:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:40:57
Amendment Manager: User entered '17 Oct 2022 23:59'	System	19 Nov 2020 03:40:57

US3172038

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:34:29

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)	24 Apr 2021 12:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53AC63F5-C23E-4645-8450-2B29D92397F9)', Time: '2021-03-01T13:21:19-05:00', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '4793f949-e07d-4ac4-a169-1ebc0496f147'	System	01 Mar 2021 18:24:53
User entered 'Yes (Y)'	System	01 Mar 2021 18:24:53

US3172038

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:34:29

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?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53AC63F5-C23E-4645-8450-2B29D92397F9)', Time: '2021-03-01T13:21:27-05:00', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '4793f949-e07d-4ac4-a169-1ebc0496f147'	System	01 Mar 2021 18:24:53
User entered 'No (N)'	System	01 Mar 2021 18:24:53

US3172038

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:34:29

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:28:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (53AC63F5-C23E-4645-8450-2B29D92397F9)', Time: '2021-03-01T13:21:30-05:00', User OID: 'PatientReportedOutcome (US3172038)', ODM File OID: '4793f949-e07d-4ac4-a169-1ebc0496f147' User entered '01 Mar 2021 13:21:30'	System	01 Mar 2021 18:24:53
	System	01 Mar 2021 18:24:53

US3172038

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:49:04
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 20:16:23

US3172038

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:49:04
User entered empty.	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 20:16:23

US3172038

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:49:04
User entered empty.	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 20:16:23

US3172038

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:49:04
User entered 'missed'	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 20:16:23

US3172038

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	08 Feb 2021 16:59:31

US3172038

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:06:15
User entered 'I'	System	08 Feb 2021 16:59:31

US3172038

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:23:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:49:04
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 20:16:33

US3172038

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:23:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:49:04
User entered empty.	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 20:16:33

US3172038

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:23:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:49:04
User entered empty.	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 20:16:33

US3172038

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:23:59
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:49:04
	(b) (4)	
User entered 'missed'	Jessie Downs (b) (4)	26 Feb 2021 20:16:33
	(b) (4)	

US3172038

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:23:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	08 Feb 2021 16:59:43

US3172038

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:23:59
User entered 'I'	System	08 Feb 2021 16:59:43

US3172038

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:23:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:49:04
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 20:16:42

US3172038

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:23:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:49:04
User entered empty.	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 20:16:42

US3172038

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:23:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:49:04
User entered empty.	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 20:16:42

US3172038

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:23:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:49:04
User entered 'missed'	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 20:16:42

US3172038

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:23:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	08 Feb 2021 16:59:50

US3172038

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:23:59
User entered 'I'	System	08 Feb 2021 16:59:50

US3172038

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:23:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	08 Feb 2021 17:00:06

US3172038

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:23:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered '05 Feb 2021'	Jessie Downs (b) (4) (b) (4)	08 Feb 2021 17:00:06

US3172038

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:23:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	08 Feb 2021 17:00:06

US3172038

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:23:59
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	08 Feb 2021 17:00:06
	(b) (4)	

US3172038

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:23:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	08 Feb 2021 17:01:07

US3172038

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:23:59
User entered 'I'	System	08 Feb 2021 17:01:07

US3172038

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:34:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:56:30
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:43:22

US3172038

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:56:30
User entered empty.	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:43:22

US3172038

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:56:30
User entered empty.	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:43:22

US3172038

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:34:29

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	16 Apr 2021 16:43:22

US3172038

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:56:30
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:43:28

US3172038

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:56:30
User entered empty.	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:43:28

US3172038

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:56:30
User entered empty.	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:43:28

US3172038

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 16:43:28

US3172038

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:29

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:56:30
User entered empty.	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:43:28

US3172038

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:29

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:56:30
User entered empty.	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:43:28

US3172038

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:29

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:56:30
User entered empty.	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:43:28

US3172038

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:56:30
User entered empty.	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:43:28

US3172038

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:29

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 16:43:28

US3172038

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:56:30
User entered empty.	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:43:28

US3172038

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 16:43:28

US3172038

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:56:30
User entered empty.	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:43:28

US3172038

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 16:43:28

US3172038

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:56:30
User entered empty.	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:43:28

US3172038

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:29

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 16:43:28

US3172038

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:34:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:56:30
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:43:56

US3172038

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:34:29

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:56:30
User entered empty.	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:43:56

US3172038

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:34:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:56:30
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:44:00

US3172038

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:34:29

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:56:30
User entered empty.	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:44:00

US3172038

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:34:29

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:56:30
User entered empty.	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:44:00

US3172038

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 16:44:00

US3172038

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:29

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:56:30
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:27:54

US3172038

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:29

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 16:27:54

US3172038

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:56:30
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:28:13

US3172038

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:29

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 15:56:30
User entered '06 Apr 2021'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:28:13

US3172038

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:29

[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 15:56:30
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:28:13

US3172038

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:56:30
User entered empty.	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:28:13

US3172038

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:56:30
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:28:40

US3172038

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:29

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Apr 2021 16:28:40

US3172038

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:34:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:51
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:56:30
	(b) (4)	
User entered 'Yes (Y)'	Jessie Downs (b) (4)	30 Mar 2021 15:10:57
	(b) (4)	

US3172038

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:34:29

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:56:30
User entered '12 Mar 2021'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 15:10:57

US3172038

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:34:29

[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 08:04:51
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:56:30
	(b) (4)	
User entered 'Clinic (Clinic)'	Jessie Downs (b) (4)	30 Mar 2021 15:10:57
	(b) (4)	

US3172038

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:34:29

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:51
User entered 'UNBLND_DECIDE'	System	30 Mar 2021 15:10:57

US3172038

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:34:29

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:56:30
User entered '06 Jan 2021'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 15:12:48

US3172038

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:34:29

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:51
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:56:30
	(b) (4)	
User entered '0'	Jessie Downs (b) (4)	30 Mar 2021 15:12:48
	(b) (4)	

US3172038

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:34:29

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:56:30
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 15:12:48

US3172038

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:34:29

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:56:30
User closed query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 12:23:08
Query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'Data updated ' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 20:59:01
User entered 'Amendment 6 or later (Amendment 6 or later)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 20:58:35
User opened query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 20:33:04
User entered empty.	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 15:12:48

US3172038

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:34:29

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:56:30
User entered '12 Mar 2021'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 15:12:48

US3172038

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:34:29

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:56:30
User entered 'Placebo (Placebo)'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 15:12:48

US3172038

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:34:29

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:56:30
User entered 'Placebo (Placebo)'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 15:12:48

US3172038

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:34:29

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:56:30
User entered 'Placebo (Placebo)'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 15:12:48

US3172038

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:34:29

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:56:30
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 15:12:48

US3172038

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:34:29

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:51
User entered '1'	System	30 Mar 2021 15:12:48

US3172038

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:34:29

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:51
User entered empty.	System	30 Mar 2021 15:12:48

US3172038

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:34:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:56:30
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 15:11:17

US3172038

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:34:29

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:56:30
User entered '12 Mar 2021'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 15:11:17

US3172038

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:34:29

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:56:30
User entered '13:30'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 15:11:17

US3172038

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:34:29

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:51
User entered '12 Mar 2021 13:30'	System	30 Mar 2021 15:11:17

US3172038

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:34:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:56:30
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 15:11:32

US3172038

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:34:29

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:56:30
User entered '12 Mar 2021'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 15:11:32

US3172038

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:34:29

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:56:30
User entered '13:31'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 15:11:32

US3172038

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:34:29

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:04:51
User entered '12 Mar 2021 13:31'	System	30 Mar 2021 15:11:32

US3172038

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:34:29

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:07:02
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:04:22
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User closed query 'Per CDM: Did the participant experience any adverse events? is recorded as "NO". However AE's are reported for this subject. Please review and update the data else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 20:29:41
Query 'Per CDM: Did the participant experience any adverse events? is recorded as "NO". However AE's are reported for this subject. Please review and update the data else clarify. Thank you.' answered with 'Data was updated.' (Site from DM).	Jessie Downs (b) (4) (b) (4)	30 Nov 2020 20:59:54
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	30 Nov 2020 20:59:46
User opened query 'Per CDM: Did the participant experience any adverse events? is recorded as "NO". However AE's are reported for this subject. Please review and update the data else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 03:35:48
User closed query 'Per CDM: Did the participant experience any adverse events? is recorded as "Yes". However there is no AE's reported for this subject. Please review and update the data else clarify. thank you.' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 20:46:13
Query 'Per CDM: Did the participant experience any adverse events? is recorded as "Yes". However there is no AE's reported for this subject. Please review and update the data else clarify. thank you.' answered with 'Data updated.' (Site from DM).	Jessie Downs (b) (4) (b) (4)	13 Nov 2020 18:00:09
DataPoint Un-verified.	Jessie Downs (b) (4) (b) (4)	13 Nov 2020 18:00:00
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	13 Nov 2020 18:00:00

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Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:34:29

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User opened query 'Per CDM: Did the participant experience any adverse events? is recorded as "Yes". However there is no AE's reported for this subject. Please review and update the data else clarify. thank you. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 04:07:55
	(b) (4), (b) (6)	12 Nov 2020 16:46:03
User entered 'Yes (Y)'	Mariete Rendon (b) (4)	02 Sep 2020 18:08:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:29

[AEID](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:29

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Renal and urinary disorders, HLGT: Urolithiasis, HLT: Renal lithiasis, PT: Nephrolithiasis, LLT: Nephrolithiasis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Apr 2021 16:37:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Apr 2021 16:37:58
Data point term sent to Coder	System	23 Apr 2021 16:37:16
DataPoint Un-verified.	Mariete Rendon (b) (4) (b) (4)	23 Apr 2021 16:37:10
Coding entries removed.	Mariete Rendon (b) (4) (b) (4)	23 Apr 2021 16:37:10
User entered 'RIGHT KIDNEY NEPHROLITHIASIS' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	23 Apr 2021 16:37:10
User coded data point as SOC: Renal and urinary disorders, HLGT: Urolithiasis, HLT: Renal lithiasis, PT: Nephrolithiasis, LLT: Nephrolithiasis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 01:22:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 01:22:52
Data point term sent to Coder	System	19 Nov 2020 01:22:09
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
Data point term sent to Coder	System	12 Nov 2020 17:26:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
User coded data point as SOC: Renal and urinary disorders, HLGT: Urolithiasis, HLT: Renal lithiasis, PT: Nephrolithiasis, LLT: Nephrolithiasis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 02:39:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 02:39:35
Data point term sent to Coder	System	06 Nov 2020 02:38:24
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
Data point term sent to Coder	System	30 Oct 2020 19:48:51
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:27:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:29

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Renal and urinary disorders, HLGT: Urolithiasis, HLT: Renal lithiasis, PT: Nephrolithiasis, LLT: Nephrolithiasis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Oct 2020 15:25:25
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Oct 2020 15:25:25
User coded data point as SOC: Renal and urinary disorders, HLGT: Urolithiasis, HLT: Renal lithiasis, PT: Nephrolithiasis, LLT: Unilateral renal calculus - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 14:08:54
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 14:08:54
Data point term sent to Coder	System	25 Sep 2020 17:58:36
Coding entries removed.	Mariete Rendon (b) (4) (b) (4)	25 Sep 2020 17:57:59
User entered 'Right Kidney ACUTE NEPHROLITHIASIS' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	25 Sep 2020 17:57:59
User coded data point as SOC: Renal and urinary disorders, HLGT: Urolithiasis, HLT: Renal lithiasis, PT: Nephrolithiasis, LLT: Nephrolithiasis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 18:48:48
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 18:48:48
Data point term sent to Coder	System	02 Sep 2020 18:15:38
User entered 'Acute Nephrolithiasis'	Mariete Rendon (b) (4) (b) (4)	02 Sep 2020 18:14:58

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:29

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
User closed query 'Should this be yes, based on protocol 8.3.2? Please verify and update as needed.' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 16:47:01
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:46:59
Query 'Should this be yes, based on protocol 8.3.2? Please verify and update as needed.' answered with 'Data updated' (Site from CRA).	Mariete Rendon (b) (4)	06 Nov 2020 21:23:34
DataPoint Un-verified.	Mariete Rendon (b) (4)	06 Nov 2020 21:23:27
User entered 'Yes (Y)' reason for change: Data Entry Error	Mariete Rendon (b) (4)	06 Nov 2020 21:23:27
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User opened query 'Should this be yes, based on protocol 8.3.2? Please verify and update as needed.' (Site from CRA).	(b) (4), (b) (6)	30 Oct 2020 19:26:08
User entered 'No (N)' reason for change: Data Entry Error	Mariete Rendon (b) (4)	25 Sep 2020 17:57:59
User entered 'Yes (Y)'	Mariete Rendon (b) (4)	02 Sep 2020 18:14:58

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:29

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:27:19
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	02 Sep 2020 18:14:58

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:29

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:27:23
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	02 Sep 2020 18:14:58

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:27:25
User entered '29 Aug 2020' reason for change: Data Entry Error	Mariete Rendon (b) (4)	21 Oct 2020 22:29:41
User entered '30 Aug 2020'	Mariete Rendon (b) (4)	02 Sep 2020 18:14:58

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:29

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:27:36
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	02 Sep 2020 18:15:24
User entered empty; reason for change Data Entry Error	Mariete Rendon (b) (4)	02 Sep 2020 18:15:24
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	02 Sep 2020 18:14:58
User entered '15:00'	Mariete Rendon (b) (4)	02 Sep 2020 18:14:58

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:29

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
User entered empty.	System	02 Sep 2020 18:15:24
User entered '30 Aug 2020 15:00'	System	02 Sep 2020 18:14:58

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:29

[Ongoing?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 20:30:05
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.' answered with 'AE is still ongoing.' (Site from DM).	Jessie Downs (b) (4) (b) (4)	30 Jan 2021 15:46:14
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 05:16:40
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:27:38
User entered 'Yes (Y)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	27 Oct 2020 20:13:34
User entered 'No (N)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	27 Oct 2020 20:12:27
User entered 'Yes (Y)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	25 Sep 2020 17:57:59
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	02 Sep 2020 18:14:58

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:29

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:27:49
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	27 Oct 2020 20:13:34
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	27 Oct 2020 20:13:34
User entered empty; reason for change Data Entry Error	Mariete Rendon (b) (4) (b) (4)	27 Oct 2020 20:13:34
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	27 Oct 2020 20:12:27
User entered '30 Aug 2020' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	27 Oct 2020 20:12:27
User entered empty; reason for change Data Entry Error	Mariete Rendon (b) (4) (b) (4)	25 Sep 2020 17:57:59
User entered '31 Aug 2020'	Mariete Rendon (b) (4) (b) (4)	02 Sep 2020 18:14:58

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:29

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:27:51
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 Sep 2020 18:15:24
User entered empty; reason for change Data Entry Error	Mariete Rendon (b) (4) (b) (4)	02 Sep 2020 18:15:24
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 Sep 2020 18:14:58
User entered '02:00'	Mariete Rendon (b) (4) (b) (4)	02 Sep 2020 18:14:58

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:29

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
User entered empty.	System	02 Sep 2020 18:15:24
User entered '31 Aug 2020 02:00'	System	02 Sep 2020 18:14:58

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:29

[Severity](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:27:53
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	Mariete Rendon (b) (4)	02 Sep 2020 20:48:19
User entered 'Grade 4 (Grade 4)'	Mariete Rendon (b) (4)	02 Sep 2020 18:14:58

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:29

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:37:50
Query 'Inpatient hospitalization qualifies as serious adverse event. Please verify and update as needed.' canceled (Site from CRA).	(b) (4), (b) (6)	30 Oct 2020 19:37:45
User opened query 'Inpatient hospitalization qualifies as serious adverse event. Please verify and update as needed.' (Site from CRA).	(b) (4), (b) (6)	30 Oct 2020 19:32:41
User closed query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).	System	02 Sep 2020 20:48:19
Query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' answered by data change (Site from System).	System	02 Sep 2020 20:48:19
User opened query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).	System	02 Sep 2020 18:14:58
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	02 Sep 2020 18:14:58

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:29

[Death](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:37:52
User entered '0'	Mariete Rendon (b) (4) (b) (4)	02 Sep 2020 18:14:58

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:29

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:37:59
User entered '0'	Mariete Rendon (b) (4) (b) (4)	02 Sep 2020 18:14:58

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
Query 'Please record inpatient hospitalization information' canceled (Site from CRA).	(b) (4), (b) (6)	30 Oct 2020 19:37:57
User opened query 'Please record inpatient hospitalization information' (Site from CRA).	(b) (4), (b) (6)	30 Oct 2020 19:34:17
User entered '0'	Mariete Rendon (b) (4) (b) (4)	02 Sep 2020 18:14:58

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:29

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:38:01
User entered empty.	Mariete Rendon (b) (4) (b) (4)	02 Sep 2020 18:14:58

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:29

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:38:02
User entered empty.	Mariete Rendon (b) (4) (b) (4)	02 Sep 2020 18:14:58

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Folder: Adverse Events

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Generated On: 09 Jun 2021 15:34:29

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:38:10
User entered empty.	Mariete Rendon (b) (4) (b) (4)	02 Sep 2020 18:14:58

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Folder: Adverse Events

Form: Adverse Events (1)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:38:04
User entered empty.	Mariete Rendon (b) (4) (b) (4)	02 Sep 2020 18:14:58

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:38:08
User entered '0'	Mariete Rendon (b) (4) (b) (4)	02 Sep 2020 18:14:58

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:38:06
User entered '0'	Mariete Rendon (b) (4) (b) (4)	02 Sep 2020 18:14:58

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:29

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:38:11
User entered '0'	Mariete Rendon (b) (4) (b) (4)	02 Sep 2020 18:14:58

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:29

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:38:15
User entered 'Not Related (NOT RELATED)'	Mariete Rendon (b) (4) (b) (4)	02 Sep 2020 18:14:58

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:38:16
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Sep 2020 18:39:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Sep 2020 18:39:31
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Mariete Rendon (b) (4)	02 Sep 2020 18:39:31
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Sep 2020 18:14:58
User entered empty.	Mariete Rendon (b) (4)	02 Sep 2020 18:14:58

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Form: Adverse Events (1)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:38:18
User entered 'Not Applicable (NOT APPLICABLE)'	Mariete Rendon (b) (4) (b) (4)	02 Sep 2020 18:14:58

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:29

None

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:38:24
User entered '0' reason for change: Data Entry Error	Mariete Rendon (b) (4)	25 Sep 2020 17:57:59
User entered '1'	Mariete Rendon (b) (4)	02 Sep 2020 18:14:58

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR - RQ: Site's response noted. However, there is still NO Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 04:00:22
Query 'Per DM CLR - RQ: Site's response noted. However, there is still NO Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'Medication is added in concomitant log. ' (Site from DM).	Jessie Downs (b) (4) (b) (4)	30 Jan 2021 15:46:47
User opened query 'Per DM CLR - RQ: Site's response noted. However, there is still NO Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 05:18:09
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	21 Nov 2020 13:20:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'Conmed updated' (Site from DM).	Mariete Rendon (b) (4) (b) (4)	27 Oct 2020 19:07:27

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EAB) (1725)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 03:44:14
User entered '1' reason for change: Data Entry Error	Mariete Rendon (b) (4)	25 Sep 2020 17:57:59
User entered '0'	Mariete Rendon (b) (4)	02 Sep 2020 18:14:58

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	21 Nov 2020 13:21:32
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
Query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' answered with 'data updated' (Site from DM).	Mariete Rendon (b) (4)	27 Oct 2020 19:12:10
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 03:44:20
User entered '1' reason for change: Data Entry Error	Mariete Rendon (b) (4)	25 Sep 2020 17:57:59
User entered '0'	Mariete Rendon (b) (4)	02 Sep 2020 18:14:58

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[Outcome](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Mariete Rendon (b) (4)	25 Sep 2020 17:57:59
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Sep 2020 18:39:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Sep 2020 18:39:31
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Mariete Rendon (b) (4)	02 Sep 2020 18:39:31
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Sep 2020 18:14:58
User entered empty.	Mariete Rendon (b) (4)	02 Sep 2020 18:14:58

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered empty.	Mariete Rendon (b) (4) (b) (4)	02 Sep 2020 18:14:58

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Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered empty.	Mariete Rendon (b) (4) (b) (4)	02 Sep 2020 18:14:58

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Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
User entered '0'	System	02 Sep 2020 18:14:58

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Folder: Adverse Events

Form: Adverse Events (1)

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Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
User entered '1'	System	06 Nov 2020 21:23:27
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
User entered '0'	System	25 Sep 2020 17:57:59
User entered '1'	System	02 Sep 2020 18:14:58

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Folder: Adverse Events

Form: Adverse Events (1)

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29

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Folder: Adverse Events

Form: Adverse Events (2)

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[AEID](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:06
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 23:59:32
User entered 'USA-US118-2020-mRNA-1273-P301000001'	System	02 Sep 2020 23:59:02
User entered 'New'	(b) (4), (b) (6)	02 Sep 2020 23:59:02

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Folder: Adverse Events

Form: Adverse Events (2)

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[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Urinary tract infections, PT: Pyelonephritis acute, LLT: Acute pyelonephritis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 01:22:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 01:22:52
Data point term sent to Coder	System	19 Nov 2020 01:22:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
Data point term sent to Coder	System	12 Nov 2020 17:26:45
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Urinary tract infections, PT: Pyelonephritis acute, LLT: Acute pyelonephritis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 02:39:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 02:39:36
Data point term sent to Coder	System	06 Nov 2020 02:38:24
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
Data point term sent to Coder	System	30 Oct 2020 19:48:51
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Urinary tract infections, PT: Pyelonephritis acute, LLT: Acute pyelonephritis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 20:39:43
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 20:39:43
Data point term sent to Coder	System	22 Oct 2020 12:35:38
Coding entries removed.	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:35:37
User entered 'ACUTE PYELONEPHRITIS (Right Kidney)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:35:37

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[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'PV query: Did the subject have a history of nephrolithiasis? If so, please add to MH eCRF. Please leave query open until answered.' (Site from Safety).	(b) (4), (b) (6)	25 Sep 2020 19:29:55
User closed query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so. Please leave query open until answered.' (Site from Safety).	(b) (4), (b) (6)	25 Sep 2020 18:12:53
Query 'PV query: Did the subject have a history of nephrolithiasis? If so, please add to MH eCRF. Please leave query open until answered.' answered with 'As per Investigator No history' (Site from Safety).	Mariete Rendon (b) (4)	25 Sep 2020 16:23:01
Query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so. Please leave query open until answered.' answered with 'Pending Medical records.' (Site from Safety).	Mariete Rendon (b) (4)	24 Sep 2020 17:19:15
User opened query 'PV query: Did the subject have a history of nephrolithiasis? If so, please add to MH eCRF. Please leave query open until answered.' (Site from Safety).	(b) (4), (b) (6)	22 Sep 2020 15:51:39
User closed query 'PV query: Did the subject have a history of nephrolithiasis? If so, please add to MH eCRF.' (Site from Safety).	(b) (4), (b) (6)	22 Sep 2020 15:51:39
User opened query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so. Please leave query open until answered.' (Site from Safety).	(b) (4), (b) (6)	22 Sep 2020 15:51:20

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[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	22 Sep 2020 15:51:20
Query 'PV query: Did the subject have a history of nephrolithiasis? If so, please add to MH eCRF.' answered with 'Unknown at this time. Pending Medical records.' (Site from Safety).	Mariete Rendon (b) (4)	21 Sep 2020 18:59:45
Query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' answered with 'Unknown at this time. Pending Medical records.' (Site from Safety).	Mariete Rendon (b) (4)	21 Sep 2020 18:59:22
User opened query 'PV query: Did the subject have a history of nephrolithiasis? If so, please add to MH eCRF.' (Site from Safety).	(b) (4), (b) (6)	17 Sep 2020 14:59:45
User opened query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	17 Sep 2020 14:59:12
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Urinary tract infections, PT: Pyelonephritis acute, LLT: Acute pyelonephritis - version MedDRA\23.0.	Coder Import (b) (4)	09 Sep 2020 16:21:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	09 Sep 2020 16:21:59
Data point term sent to Coder	System	09 Sep 2020 16:21:00
Coding entries removed.	Mariete Rendon (b) (4)	09 Sep 2020 16:20:21
User entered 'ACUTE PYELONEPHRITIS' reason for change: Data Entry Error	Mariete Rendon (b) (4)	09 Sep 2020 16:20:21

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Folder: Adverse Events

Form: Adverse Events (2)

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[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Renal and urinary disorders, HLGT: Urolithiases, HLT: Renal lithiasis, PT: Nephrolithiasis, LLT: Nephrolithiasis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 18:48:47
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 18:48:47
Data point term sent to Coder	System	02 Sep 2020 18:26:02
User entered 'ACUTE EXACERBATION OF NEPHROLITHIASIS'	Mariete Rendon (b) (4) (b) (4)	02 Sep 2020 18:25:17

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:29

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 21:49:28
User closed query 'All unscheduled visit to a healthcare practitioner (AEs and SAEs included) are considered MAAEs per protocol. Please update response.' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 21:49:26
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4)	18 Feb 2021 21:20:58
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4)	30 Jan 2021 15:50:21
Query 'All unscheduled visit to a healthcare practitioner (AEs and SAEs included) are considered MAAEs per protocol. Please update response.' answered by data change (Site from CRA).	System	30 Jan 2021 15:49:41
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4)	30 Jan 2021 15:49:41
User opened query 'All unscheduled visit to a healthcare practitioner (AEs and SAEs included) are considered MAAEs per protocol. Please update response.' (Site from CRA).	(b) (4), (b) (6)	07 Dec 2020 00:06:57
User closed query 'Medically attended AEs are defined as any AEs that lead to an unscheduled visit to a healthcare practitioner. If you select yes, will it trigger another form to be completed?' (Site from CRA).	(b) (4), (b) (6)	07 Dec 2020 00:06:57
Query 'Medically attended AEs are defined as any AEs that lead to an unscheduled visit to a healthcare practitioner. If you select yes, will it trigger another form to be completed?' answered with 'No other form is triggered if yes is selected.' (Site from CRA).	Mariete Rendon (b) (4)	30 Nov 2020 20:36:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
User opened query 'Medically attended AEs are defined as any AEs that lead to an unscheduled visit to a healthcare practitioner. If you select yes, will it trigger another form to be completed?' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 17:10:59

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Folder: Adverse Events

Form: Adverse Events (2)

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User closed query 'Should this be yes?' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 17:10:59
Query 'Should this be yes?' answered with 'SAE involves (MAAE) please advise if we can choose more than one option? ' (Site from CRA).	Mariete Rendon (b) (4)	06 Nov 2020 21:24:31
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:15
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User opened query 'Should this be yes?' (Site from CRA).	(b) (4), (b) (6)	30 Oct 2020 19:39:02
User entered 'No (N)' reason for change: Data Entry Error	Mariete Rendon (b) (4)	09 Sep 2020 16:20:21
User entered 'Yes (Y)'	Mariete Rendon (b) (4)	02 Sep 2020 18:25:17

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Folder: Adverse Events

Form: Adverse Events (2)

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	02 Sep 2020 18:25:17

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Folder: Adverse Events

Form: Adverse Events (2)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	02 Sep 2020 18:25:17

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered '01 Sep 2020' reason for change: Data Entry Error	Mariete Rendon (b) (4)	09 Sep 2020 16:20:21
User entered '31 Aug 2020'	Mariete Rendon (b) (4)	02 Sep 2020 18:25:17

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:29

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
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	02 Sep 2020 18:26:10
User entered empty; reason for change Data Entry Error	Mariete Rendon (b) (4)	02 Sep 2020 18:26:10
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	02 Sep 2020 18:25:17
User entered '04:00'	Mariete Rendon (b) (4)	02 Sep 2020 18:25:17

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:29

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
User entered empty.	System	02 Sep 2020 18:26:10
User entered '31 Aug 2020 04:00'	System	02 Sep 2020 18:25:17

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:29

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered 'No (N)' reason for change: Data Entry Error	Mariete Rendon (b) (4)	27 Oct 2020 19:15:28
User entered 'Yes (Y)'	Mariete Rendon (b) (4)	02 Sep 2020 18:25:17

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:20:24
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 17:19:53
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:33
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered '26 Sep 2020' reason for change: Data Entry Error	Mariete Rendon (b) (4)	27 Oct 2020 19:15:28
User entered empty.	Mariete Rendon (b) (4)	02 Sep 2020 18:25:17

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Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:29

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered empty.	Mariete Rendon (b) (4) (b) (4)	02 Sep 2020 18:25:17

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Form: Adverse Events (2)

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' canceled (Site from Safety).	(b) (4), (b) (6)	29 Oct 2020 22:33:18
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	17 Sep 2020 15:00:16
User entered empty.	System	02 Sep 2020 18:25:17

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:29

[Severity](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	Jessie Downs (b) (4)	10 Sep 2020 23:26:47
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	Mariete Rendon (b) (4)	09 Sep 2020 16:20:21
User entered 'Grade 4 (Grade 4)'	Mariete Rendon (b) (4)	02 Sep 2020 18:25:17

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Folder: Adverse Events

Form: Adverse Events (2)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	02 Sep 2020 18:25:17

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Folder: Adverse Events

Form: Adverse Events (2)

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[Death](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered '0'	Mariete Rendon (b) (4) (b) (4)	02 Sep 2020 18:25:17

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Folder: Adverse Events

Form: Adverse Events (2)

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[Life threatening](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered '1' reason for change: Data Entry Error	Mariete Rendon (b) (4)	09 Sep 2020 16:20:21
User entered '0'	Mariete Rendon (b) (4)	02 Sep 2020 18:25:17

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Folder: Adverse Events

Form: Adverse Events (2)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).		09 Sep 2020 16:29:51
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).		09 Sep 2020 16:29:51
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	02 Sep 2020 18:25:17
User entered 'I'	Mariete Rendon (b) (4) (b) (4)	02 Sep 2020 18:25:17

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:29

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered '01 Sep 2020' reason for change: Data Entry Error	Mariete Rendon (b) (4)	09 Sep 2020 16:29:51
User entered '31 Aug 2020'	Mariete Rendon (b) (4)	02 Sep 2020 18:25:17

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:29

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered '04 Sep 2020' reason for change: Data Entry Error	Mariete Rendon (b) (4)	09 Sep 2020 16:29:51
User entered empty.	Mariete Rendon (b) (4)	02 Sep 2020 18:25:17

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Folder: Adverse Events

Form: Adverse Events (2)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User closed query 'PV Query: Please confirm if vital signs remained stable during ICU admission. If not, please provide abnormal vital signs, along with treatment. Please leave query open until answered.' (Site from Safety).	(b) (4), (b) (6)	25 Sep 2020 18:13:09
Query 'PV Query: Please confirm if vital signs remained stable during ICU admission. If not, please provide abnormal vital signs, along with treatment. Please leave query open until answered.' answered with 'Unknown pending Medical Records.' (Site from Safety).	Mariete Rendon (b) (4) (b) (4)	24 Sep 2020 17:22:51
User opened query 'PV Query: Please confirm if vital signs remained stable during ICU admission. If not, please provide abnormal vital signs, along with treatment. Please leave query open until answered.' (Site from Safety).	(b) (4), (b) (6)	22 Sep 2020 15:52:02
User closed query 'PV Query: Please confirm if vital signs remained stable during ICU admission. If not, please provide abnormal vital signs, along with treatment.' (Site from Safety).	(b) (4), (b) (6)	22 Sep 2020 15:52:02
Query 'PV Query: Please confirm if vital signs remained stable during ICU admission. If not, please provide abnormal vital signs, along with treatment.' answered with 'Unknown at this time. Pending Medical records.' (Site from Safety).	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 18:59:52
User opened query 'PV Query: Please confirm if vital signs remained stable during ICU admission. If not, please provide abnormal vital signs, along with treatment.' (Site from Safety).	(b) (4), (b) (6)	17 Sep 2020 15:01:28
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	02 Sep 2020 18:25:17

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Form: Adverse Events (2)

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Number of Days in ICU

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User closed query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' (Site from System).	System	03 Sep 2020 06:09:15
Query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' answered by data change (Site from System).	System	03 Sep 2020 06:09:15
User entered '3' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 06:09:15
User opened query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' (Site from System).	System	02 Sep 2020 18:25:17
User entered empty.	Mariete Rendon (b) (4) (b) (4)	02 Sep 2020 18:25:17

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered '0'	Mariete Rendon (b) (4) (b) (4)	02 Sep 2020 18:25:17

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered '0'	Mariete Rendon (b) (4) (b) (4)	02 Sep 2020 18:25:17

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Folder: Adverse Events

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered '0'	Mariete Rendon (b) (4) (b) (4)	02 Sep 2020 18:25:17

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Folder: Adverse Events

Form: Adverse Events (2)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
Query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	25 Sep 2020 13:13:18
User opened query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	09 Sep 2020 16:20:21
User entered 'Not Related (NOT RELATED)'	Mariete Rendon (b) (4) (b) (4)	02 Sep 2020 18:25:17

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:29

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered 'Not Related (NOT RELATED)'	Mariete Rendon (b) (4) (b) (4)	02 Sep 2020 18:25:17

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:29

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User closed query 'Action Taken with Investigational System Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).		21 Oct 2020 14:00:16
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered by data change (Site from System).	System	21 Oct 2020 14:00:16
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	08 Oct 2020 13:47:36
User closed query 'Per DM CLR: Action Taken with Investigational Product=Investigational Product Withdrawn. Ensure this is reflected in treatment discontinuation if applicable. Review and update. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 14:47:47
Query 'Per DM CLR: Action Taken with Investigational Product=Investigational Product Withdrawn. Ensure this is reflected in treatment discontinuation if applicable. Review and update. Else, clarify.' answered with 'Waiting on medical records' (Site from DM).	Jessie Downs (b) (4)	29 Sep 2020 21:43:07

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Folder: Adverse Events

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Generated On: 09 Jun 2021 15:34:29

Action taken with investigational product

Audit	User	Time (GMT)
User closed query 'Per CDM: Response noted. Only one AE should be recorded as Study Drug Withdrawn. However for this subject AE in log line 3 also indicated "Action taken with investigational product is Investigational Product Withdrawn." Please review and update the data accordingly else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 03:40:34
User opened query 'Per DM CLR: Action Taken with Investigational Product=Investigational Product Withdrawn. Ensure this is reflected in treatment discontinuation if applicable. Review and update. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 02:25:46
User closed query 'PV query: How many days after second dose of mRNA-1273 or placebo did the patient experienced the SAE?' (Site from Safety).	(b) (4), (b) (6)	25 Sep 2020 19:29:49
Query 'Per CDM: Response noted. Only one AE should be recorded as Study Drug Withdrawn. However for this subject AE in log line 3 also indicated "Action taken with investigational product is Investigational Product Withdrawn." Please review and update the data accordingly else clarify. Thank you.' answered with 'Data correct as is' (Site from DM).	Mariete Rendon (b) (4) (b) (4)	25 Sep 2020 16:25:58
Query 'PV query: How many days after second dose of mRNA-1273 or placebo did the patient experienced the SAE?' answered with '2nd dose was ND. Subject was at the hospital recovering.' (Site from Safety).	Mariete Rendon (b) (4) (b) (4)	25 Sep 2020 16:25:47
User opened query 'PV query: How many days after second dose of mRNA-1273 or placebo did the patient experienced the SAE?' (Site from Safety).	(b) (4), (b) (6)	17 Sep 2020 14:59:34
User opened query 'Per CDM: Response noted. Only one AE should be recorded as Study Drug Withdrawn. However for this subject AE in log line 3 also indicated "Action taken with investigational product is Investigational Product Withdrawn." Please review and update the data accordingly else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 03:17:33
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	09 Sep 2020 16:20:21

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EAB) (1725)

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Form: Adverse Events (2)

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Action taken with investigational product

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Mariete Rendon (b) (4) (b) (4)	02 Sep 2020 18:25:17

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:29

None

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered '0'	Mariete Rendon (b) (4) (b) (4)	02 Sep 2020 18:25:17

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:29

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:41:40
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 19:41:37
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User closed query 'PV Query: Please provide treatment given for the event. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). Please leave query open until answered.' (Site from Safety).	(b) (4), (b) (6)	25 Sep 2020 18:13:32
Query 'PV Query: Please provide treatment given for the event. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). Please leave query open until answered.' answered with 'Unknown pending Medical Records.' (Site from Safety).	Mariete Rendon (b) (4)	24 Sep 2020 17:23:06
User opened query 'PV Query: Please provide treatment given for the event. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). Please leave query open until answered.' (Site from Safety).	(b) (4), (b) (6)	22 Sep 2020 15:53:08
User closed query 'PV Query: Please provide treatment given for the event. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). Please leave query open until answered.' (Site from Safety).	(b) (4), (b) (6)	22 Sep 2020 15:53:08

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:29

[Concomitant Medication](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide treatment given for the event. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).' answered with 'Unknown at this time. Pending Medical records.' (Site from Safety).	Mariete Rendon (b) (4)	21 Sep 2020 19:00:16
User opened query 'PV Query: Please provide treatment given for the event. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).' (Site from Safety).	(b) (4), (b) (6)	17 Sep 2020 15:00:41
User entered '1' reason for change: Data Entry Error	Mariete Rendon (b) (4)	09 Sep 2020 16:20:21
User entered '0'	Mariete Rendon (b) (4)	02 Sep 2020 18:25:17

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:29

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered 'I'	Mariete Rendon (b) (4) (b) (4)	02 Sep 2020 18:25:17

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:29

[Outcome](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User closed query 'PV query: Please provide the final outcome, when available. Please do not response to this query until the event has ended. (event of acute pyelonephritis)' (Site from Safety).	(b) (4), (b) (6)	28 Oct 2020 13:25:23
Query 'PV query: Please provide the final outcome, when available. Please do not response to this query until the event has ended. (event of acute pyelonephritis)' answered with 'SAE recovered/resolved' (Site from Safety).	Mariete Rendon (b) (4)	27 Oct 2020 19:16:14
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Mariete Rendon (b) (4)	27 Oct 2020 19:15:28
User opened query 'PV query: Please provide the final outcome, when available. Please do not response to this query until the event has ended. (event of acute pyelonephritis)' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 21:31:28
User closed query 'PV query: Please provide the final outcome, when available. Please do not response to this query until the event has ended. (event of acute pyelonephritis)' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 14:08:52
Query 'PV query: Please provide the final outcome, when available. Please do not response to this query until the event has ended. (event of acute pyelonephritis)' answered with 'Still pending Medical Records.' (Site from Safety).	Mariete Rendon (b) (4)	02 Oct 2020 18:34:06
User opened query 'PV query: Please provide the final outcome, when available. Please do not response to this query until the event has ended. (event of acute pyelonephritis)' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 18:22:12

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Folder: Adverse Events

Form: Adverse Events (2)

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[Outcome](#)

Audit	User	Time (GMT)
User closed query 'PV query: Please provide the final outcome, when available. Please do not response to this query until the event has ended.' (Site from Safety).	(b) (4), (b) (6)	25 Sep 2020 18:13:38
Query 'PV query: Please provide the final outcome, when available. Please do not response to this query until the event has ended.' answered with 'Unknown pending Medical Records.' (Site from Safety).	Mariete Rendon (b) (4)	24 Sep 2020 17:23:10
User opened query 'PV query: Please provide the final outcome, when available. Please do not response to this query until the event has ended.' (Site from Safety).	(b) (4), (b) (6)	17 Sep 2020 15:00:28
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	Jessie Downs (b) (4)	10 Sep 2020 23:27:52
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Mariete Rendon (b) (4)	02 Sep 2020 18:25:17

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Form: Adverse Events (2)

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered empty.	Mariete Rendon (b) (4) (b) (4)	02 Sep 2020 18:25:17

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Form: Adverse Events (2)

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[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:16:48
User closed query 'Per CDM: SAE Narrative = PERCUTANEOUS NEPHROSTOMY TUBE. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 06:08:13
User closed query 'Per CDM : SAE Narrative = SCHEDULE A URETHOSCOPY. Please confirm if this was already performed and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 06:08:06
User closed query 'Per CDM: SAE Narrative = SECONDARY HYDRONEPHOROSIS. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 06:07:58
User closed query 'Per CDM: Narrative suggest that subject had NEPHROSTOGRAM ANTEGRADE UROGRAPHY. However, this is not recorded as Concomittant Procedure. Please review and add all pertinent information in their respective eCRF as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 06:07:49
Query 'Per CDM: SAE Narrative = SECONDARY HYDRONEPHOROSIS. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate. ' answered with 'Data confirmed as entered. ' (Site from DM).	Jessie Downs (b) (4)	25 Feb 2021 20:11:55
Query 'Per CDM : SAE Narrative = SCHEDULE A URETHOSCOPY. Please confirm if this was already performed and ensure that this is captured in the appropriate eCRF. ' answered with 'Data was updated.' (Site from DM).	Jessie Downs (b) (4)	25 Feb 2021 20:11:32
Query 'Per CDM: SAE Narrative = PERCUTANEOUS NEPHROSTOMY TUBE. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'data was updated.' (Site from DM).	Jessie Downs (b) (4)	25 Feb 2021 20:09:54

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Form: Adverse Events (2)

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[Narrative](#)

Audit	User	Time (GMT)
Query 'Per CDM: Narrative suggest that subject had NEPHROSTOGRAM ANTEGRADE UROGRAPHY. However, this is not recorded as Concomittant Procedure. Please review and add all pertinent information in their respective eCRF as appropriate. Otherwise, clarify. ' answered with 'data updated ' (Site from DM).	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 20:07:48
User opened query 'Per CDM : SAE Narrative = SCHEDULE A URETHOSCOPY. Please confirm if this was already performed and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 21:51:19
User closed query 'Per DM CLR: SAE Narrative = SCHEDULE A URETHOSCOPY. Please confirm if this was already performed and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 21:50:59
User opened query 'Per CDM: SAE Narrative = SECONDARY HYDRONEPHOROSIS. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 21:50:46
User closed query 'Per DM CLR: SAE Narrative = SECONDARY HYDRONEPHOROSIS. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 21:50:27
User opened query 'Per CDM: SAE Narrative = PERCUTANEOUS NEPHROSTOMY TUBE. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 21:50:13
User closed query 'Per DM CLR: SAE Narrative = PERCUTANEOUS NEPHROSTOMY TUBE. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 21:49:48

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: SAE Narrative = SUBJECT EMERGENCY CONTACT REPORTED THAT THE PATIENT WAS HOSPITALIZED ON SAME DATE 31AUG2020. However, Hospitalization admission was recorded as 01SEP2020. Please review and reconcile data as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 21:49:03
User opened query 'Per CDM: Narrative suggest that subject had NEPHROSTOGRAM ANTEGRADE UROGRAPHY. However, this is not recorded as Concomittant Procedure. Please review and add all pertinent information in their respective eCRF as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 17:33:42
User closed query 'Per DM CLR: Narrative suggest that subject had NEPHROSTOGRAM ANTEGRADE UROGRAPHY. However, this is not recorded as Concomittant Procedure. Please review and add all pertinent information in their respective eCRF as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 17:32:58
Query 'Per DM CLR: SAE Narrative = SCHEDULE A URETHOSCOPY. Please confirm if this was already performed and ensure that this is captured in the appropriate eCRF. ' answered with 'Pending medical records.' (Site from DM).	Jessie Downs (b) (4)	18 Feb 2021 21:21:28
Query 'Per DM CLR: SAE Narrative = SECONDARY HYDRONEPHOROSIS. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' answered with 'Pending medical records.' (Site from DM).	Jessie Downs (b) (4)	18 Feb 2021 21:21:26
Query 'Per DM CLR: SAE Narrative = PERCUTANEOUS NEPHROSTOMY TUBE. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Pending medical records.' (Site from DM).	Jessie Downs (b) (4)	18 Feb 2021 21:21:23

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[Narrative](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: SAE Narrative = SUBJECT EMERGENCY CONTACT REPORTED THAT THE PATIENT WAS HOSPITALIZED ON SAME DATE 31AUG2020. However, Hospitalization admission was recorded as 01SEP2020. Please review and reconcile data as appropriate. ' answered with 'Pending medical records.' (Site from DM).	Jessie Downs (b) (4)	18 Feb 2021 21:21:20
Query 'Per DM CLR: Narrative suggest that subject had NEPHROSTOGRAM ANTEGRADE UROGRAPHY. However, this is not recorded as Concomittant Procedure. Please review and add all pertinent information in their respective eCRF as appropriate. Otherwise, clarify. ' answered with 'Pending medical records.' (Site from DM).	Jessie Downs (b) (4)	18 Feb 2021 21:21:17
DataPoint Un-verified.	(b) (4), (b) (6)	13 Jan 2021 19:25:17
User opened query 'Per DM CLR: SAE Narrative = SCHEDULE A URETHOSCOPY. Please confirm if this was already performed and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 05:20:22
User opened query 'Per DM CLR: SAE Narrative = SECONDARY HYDRONEPHOROSIS. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 05:20:15
User opened query 'Per DM CLR: SAE Narrative = PERCUTANEOUS NEPHROSTOMY TUBE. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 05:20:09
User opened query 'Per DM CLR: SAE Narrative = SUBJECT EMERGENCY CONTACT REPORTED THAT THE PATIENT WAS HOSPITALIZED ON SAME DATE 31AUG2020. However, Hospitalization admission was recorded as 01SEP2020. Please review and reconcile data as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 05:19:27

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per CDM RQ: Please keep query open until medical records have been received and eCRFs have been updated appropriately. Thank you' (Site from DM).	(b) (4), (b) (6)	29 Dec 2020 16:04:18
User opened query 'Per DM CLR: Narrative suggest that subject had NEPHROSTOGRAM ANTEGRADE UROGRAPHY. However, this is not recorded as Concomittant Procedure. Please review and add all pertinent information in their respective eCRF as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 13:25:19
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:55:21
Query 'Per CDM RQ: Please keep query open until medical records have been received and eCRFs have been updated appropriately. Thank you' answered with 'narrative updated as much as possible. unable to complete narrative not enough space. Please advise?' (Site from DM).	Mariete Rendon (b) (4) (b) (4)	11 Nov 2020 20:28:59

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT EMERGENCY CONTACT REPORTED THAT THE PATIENT WAS HOSPITALIZED ON SAME DATE 31AUG2020 IN ICU WITH ACUTE EXACERBATION OF NEPHROLITHIASIS AND THAT SYMPTOMS WERE GETTING WORSE. SUBJECT WAS TRANSFERED TO HOSPITAL VIA RESCUE. RECORDS WILL BE REQUESTED AS SOON AS PATIENT IS DISCHARGED. 09SEP2020-DISCHARGED RECORDS RECEIVED BY EMAIL FROM SUBJECT. SHE HAS PYELONEPHRITIS CONFIRMED BY NEPHROSTOGRAM ANTEGRADE UROGRAPHY ON 01SEP2020 (AT ADMISSION). THIS EVENT LEAD TO A SEPTIC SHOCK, ELEVATED TROPINONINS ANS SEPTIC ACIDOSIS BEGINNING ICU ADMISSION FOR IV ABS, IV FLUIDS, AND PERCUTANEOUS NEPHROSTAMY TUBE FOR RIGHT KIDNEY STONE/ RIGHT URETER DEOMPRESSION. STILL WAITING FOR RECORDS FROM HOSPITAL FOR DETAILS. RECOVERING AT HOME WITH NURSING CARE TO COMPLETE ABS IV TREATMENT AND DRAINAGE/ WOUND CARE WILL FOLLOW UP. DISCUSSED WITH PI WILL DISCHARGE IP TREATMENT. INITIAL SIGNS AND SYMPTOMS: RIGHT UPPER QUADRANT ABDOMEN PAIN, TACHYCHARDIA, FEVER, HYPOSTENSION, DIAPHORESIS, TRACHYPNEA, ANXIETY. admission 31AUG2020-Discharged 04SEP2020 subject admitted due to recurrent R flank pain and fever for 2 days before admission. she was found to have urosepsis with E. Coli bacteria from pyelorephitis with obstructing R proximal ureteral stone and high R renal stone burden with secondary hydronephrosis. chest x-ray done on 01SEP2020 with asymptomatic elevation of R hemidiaphragm. CT chest, abdominal pelvis with contrast confirmed the R pyelophritis findings and the obstruction renal calculus at R proximal uterus cruising	Mariete Rendon (b) (4)	11 Nov 2020 20:24:10

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Audit	User	Time (GMT)
hydronephrosis. CT Brain without contrast 01SEP2020 without acute findings. Subject was discharged home on 04SEP20 on a stable condition with PO double strength bactrin BID to complete 14 days of ABs course 01SEP-18SEP she left the hospital with a nephrostomy tube and urologist follow up to schedule a urethoscopy for removal of renal stones. Unable to complete Narrative due to not enough space.' reason for change: Data Entry Error DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 19:41:53
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User closed query 'PV Query: Please confirm if vital signs remained stable during ICU admission. If not, please provide abnormal vital signs, along with treatment. Please leave query open until answered.' (Site from Safety).	(b) (4), (b) (6)	28 Oct 2020 13:25:13
User closed query 'PV Query: Please confirm if percutaneous drain was a one-time drain, or if drainage catheter was left in place upon discharge.' (Site from Safety).	(b) (4), (b) (6)	28 Oct 2020 13:25:12
User closed query 'PV Query: Please provide initial signs and symptoms experienced by the subject.' (Site from Safety).	(b) (4), (b) (6)	28 Oct 2020 13:25:10
User closed query 'PV Query: Please provide treatment given for the event. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). Please leave query open until answered.' (Site from Safety).	(b) (4), (b) (6)	28 Oct 2020 13:25:08
Query 'PV Query: Please confirm if vital signs remained stable during ICU admission. If not, please provide abnormal vital signs, along with treatment. Please leave query open until answered.' answered with 'vitals stable in ICU' (Site from Safety).	Mariete Rendon (b) (4) (b) (4)	27 Oct 2020 20:25:45

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Form: Adverse Events (2)

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Audit	User	Time (GMT)
Query 'PV Query: Please confirm if percutaneous drain was a one-time drain, or if drainage catheter was left in place upon discharge.' answered with 'percutaneous nephrostomy tube from 09/1/2020-09/22/2020.' (Site from Safety).	Mariete Rendon (b) (4)	27 Oct 2020 20:25:25
Query 'PV Query: Please provide initial signs and symptoms experienced by the subject.' answered with 'Data updated' (Site from Safety).	Mariete Rendon (b) (4)	27 Oct 2020 20:24:42
User entered 'SUBJECT EMERGENCY CONTACT REPORTED THAT THE PATIENT WAS HOSPITALIZED ON SAME DATE 31AUG2020 IN ICU WITH ACUTE EXACERBATION OF NEPHROLITHIASIS AND THAT SYMPTOMS WERE GETTING WORSE. SUBJECT WAS TRANSFERED TO HOSPITAL VIA RESCUE. RECORDS WILL BE REQUESTED AS SOON AS PATIENT IS DISCHARGED. 09SEP2020-DISCHARGED RECORDS RECEIVED BY EMAIL FROM SUBJECT. SHE HAS PYELONEPHRITIS CONFIRMED BY NEPHROSTOGRAM ANTEGRADE UROGRAPHY ON 01SEP2020 (AT ADMISSION). THIS EVENT LEAD TO A SEPTIC SHOCK, ELEVATED TROPINONINS ANS SEPTIC ACIDOSIS BEGINNING ICU ADMISSION FOR IV ABS, IV FLUIDS, AND PERCUTANEOUS NEPHROSTAMY TUBE FOR RIGHT KIDNEY STONE/ RIGHT URETER DEOMPRESSION. STILL WAITING FOR RECORDS FROM HOSPITAL FOR DETAILS. RECOVERING AT HOME WITH NURSING CARE TO COMPLETE ABS IV TREATMENT AND DRAINAGE/ WOUND CARE WILL FOLLOW UP. DISCUSSED WITH PI WILL DISCHARGE IP TREATMENT. initial signs and symptoms: right upper quadrant abdomen pain, tachychardia, fever, hypostension, diaphoresis, trachypnea, anxiety.' reason for change: Data Entry Error	Mariete Rendon (b) (4)	27 Oct 2020 20:24:35

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Folder: Adverse Events

Form: Adverse Events (2)

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Audit	User	Time (GMT)
User entered 'SUBJECT EMERGENCY CONTACT REPORTED THAT THE PATIENT WAS HOSPITALIZED ON SAME DATE 31AUG2020 IN ICU WITH ACUTE EXACERBATION OF NEPHROLITHIASIS AND THAT SYMPTOMS WERE GETTING WORSE. SUBJECT WAS TRANSFERED TO HOSPITAL VIA RESCUE. RECORDS WILL BE REQUESTED AS SOON AS PATIENT IS DISCHARGED. 09SEP2020-DISCHARGED RECORDS RECEIVED BY EMAIL FROM SUBJECT. SHE HAS PYELONEPHRITIS CONFIRMED BY NEPHROSTOGRAM ANTEGRADE UROGRAPHY ON 01SEP2020 (AT ADMISSION). THIS EVENT LEAD TO A SEPTIC SHOCK, ELEVATED TROPINONINS ANS SEPTIC ACIDOSIS BEGINNING ICU ADMISSION FOR IV ABS, IV FLUIDS, AND PERCUTANEOUS nephrostomy tube for right kidney stone/ right ureter decompression. STILL WAITING FOR RECORDS FROM HOSPITAL FOR DETAILS. RECOVERING AT HOME WITH NURSING CARE TO COMPLETE ABS IV TREATMENT AND DRAINAGE/ WOUND CARE WILL FOLLOW UP. DISCUSSED WITH PI WILL DISCHARGE IP TREATMENT.' reason for change: Data Entry Error	Mariete Rendon (b) (4)	27 Oct 2020 19:23:39
Query 'PV Query: Please provide treatment given for the event. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). Please leave query open until answered.' answered with 'updated in conmed log' (Site from Safety).	Mariete Rendon (b) (4)	27 Oct 2020 19:19:09

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Form: Adverse Events (2)

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Audit	User	Time (GMT)
User entered 'SUBJECT EMERGENCY CONTACT REPORTED THAT THE PATIENT WAS HOSPITALIZED ON SAME DATE 31AUG2020 IN ICU WITH ACUTE EXACERBATION OF NEPHROLITHIASIS AND THAT SYMPTOMS WERE GETTING WORSE. SUBJECT WAS TRANSFERED TO HOSPITAL VIA RESCUE. RECORDS WILL BE REQUESTED AS SOON AS PATIENT IS DISCHARGED. 09SEP2020-DISCHARGED RECORDS RECEIVED BY EMAIL FROM SUBJECT. SHE HAS PYELONEPHRITIS CONFIRMED BY NEPHROSTOGRAM ANTEGRADE UROGRAPHY ON 01SEP2020 (AT ADMISSION). THIS EVENT LEAD TO A SEPTIC SHOCK, ELEVATED TROPINONINS ANS SEPTIC ACIDOSIS BEGGINING ICU ADMISSION FOR IV ABS, IV FLUIDS, AND PERCUTANEOUS DRAINAGE. STILL WAITING FOR RECORDS FROM HOSPITAL FOR DETAILS. RECOVERING AT HOME WITH NURSING CARE TO COMPLETE ABS IV TREATMENT AND DRAINAGE/ WOUND CARE WILL FOLLOW UP. DISCUSSED WITH PI WILL DISCHARGE IP TREATMENT.' reason for change: Data Entry Error	Mariete Rendon (b) (4)	27 Oct 2020 19:18:56
User opened query 'PV Query: Please confirm if vital signs remained stable during ICU admission. If not, please provide abnormal vital signs, along with treatment. Please leave query open until answered.' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 21:32:27
User opened query 'PV Query: Please confirm if percutaneous drain was a one-time drain, or if drainage catheter was left in place upon discharge.' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 21:32:14
User opened query 'PV Query: Please provide initial signs and symptoms experienced by the subject.' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 21:32:01

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Audit	User	Time (GMT)
User opened query 'PV Query: Please provide treatment given for the event. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). Please leave query open until answered.' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 21:31:44
User opened query 'Per CDM RQ: Please keep query open until medical records have been received and eCRFs have been updated appropriately. Thank you' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 14:52:16
User closed query 'Per DM CLR: SAE Narrative contains medications and procedures. Please make sure that these information are recorded in their respective eCRFs. Otherwise, clarify the inconsistencies.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 14:52:16
User closed query 'PV Query: Please provide initial signs and symptoms experienced by the subject.' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 14:09:02
User closed query 'PV Query: Please confirm if vital signs remained stable during ICU admission. If not, please provide abnormal vital signs, along with treatment. Please leave query open until answered.' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 14:08:58
User closed query 'PV Query: Please confirm if percutaneous drain was a one-time drain, or if drainage catheter was left in place upon discharge.' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 14:08:56
User closed query 'PV Query: Please provide treatment given for the event. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). Please leave query open until answered.' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 14:08:54
Query 'PV Query: Please confirm if vital signs remained stable during ICU admission. If not, please provide abnormal vital signs, along with treatment. Please leave query open until answered.' answered with 'Still pending Medical Records.' (Site from Safety).	Mariete Rendon (b) (4) (b) (4)	02 Oct 2020 18:34:25

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Audit	User	Time (GMT)
Query 'PV Query: Please confirm if percutaneous drain was a one-time drain, or if drainage catheter was left in place upon discharge.' answered with 'Still pending Medical Records.' (Site from Safety).	Mariete Rendon (b) (4)	02 Oct 2020 18:34:20
Query 'PV Query: Please provide initial signs and symptoms experienced by the subject.' answered with 'Still pending Medical Records.' (Site from Safety).	Mariete Rendon (b) (4)	02 Oct 2020 18:34:16
Query 'PV Query: Please provide treatment given for the event. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). Please leave query open until answered.' answered with 'Still pending Medical Records.' (Site from Safety).	Mariete Rendon (b) (4)	02 Oct 2020 18:34:11
User opened query 'PV Query: Please confirm if vital signs remained stable during ICU admission. If not, please provide abnormal vital signs, along with treatment. Please leave query open until answered.' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 18:24:15
User opened query 'PV Query: Please confirm if percutaneous drain was a one-time drain, or if drainage catheter was left in place upon discharge.' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 18:23:21
User opened query 'PV Query: Please provide initial signs and symptoms experienced by the subject.' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 18:23:09
User opened query 'PV Query: Please provide treatment given for the event. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). Please leave query open until answered.' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 18:22:45
User closed query 'PV Query: Please provide initial signs and symptoms experienced by the subject.' (Site from Safety).	(b) (4), (b) (6)	30 Sep 2020 12:28:48
Query 'Per DM CLR: SAE Narrative contains medications and procedures. Please make sure that these information are recorded in their respective eCRFs. Otherwise, clarify the inconsistencies.' answered with 'Waiting on medical records' (Site from DM).	Jessie Downs (b) (4)	29 Sep 2020 21:43:28

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Audit	User	Time (GMT)
User opened query 'Per DM CLR: SAE Narrative contains medications and procedures. Please make sure that these information are recorded in their respective eCRFs. Otherwise, clarify the inconsistencies.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 02:26:03
Query 'PV Query: Please provide initial signs and symptoms experienced by the subject.' answered with 'Pending' (Site from Safety).	Mariete Rendon (b) (4)	28 Sep 2020 17:49:28
User closed query 'PV Query: Please provide any relevant laboratory/diagnostic test results (i.e. urinalysis, urine/blood culture, lactic acid, CRP, WBC, ABG, troponins, serum electrolytes, etc). Please include units and reference ranges when applicable. Please leave query open until answered.' (Site from Safety).	(b) (4), (b) (6)	25 Sep 2020 18:13:48
User closed query 'PV Query: Please confirm if percutaneous drain was a one-time drain, or if drainage catheter was left in place upon discharge.' (Site from Safety).	(b) (4), (b) (6)	25 Sep 2020 18:13:47
Query 'PV Query: Please provide any relevant laboratory/diagnostic test results (i.e. urinalysis, urine/blood culture, lactic acid, CRP, WBC, ABG, troponins, serum electrolytes, etc). Please include units and reference ranges when applicable. Please leave query open until answered.' answered with 'Unknown pending Medical Records.' (Site from Safety).	Mariete Rendon (b) (4)	24 Sep 2020 17:23:26
Query 'PV Query: Please confirm if percutaneous drain was a one-time drain, or if drainage catheter was left in place upon discharge.' answered with 'Unknown pending Medical Records.' (Site from Safety).	Mariete Rendon (b) (4)	24 Sep 2020 17:23:22
User opened query 'PV Query: Please provide any relevant laboratory/diagnostic test results (i.e. urinalysis, urine/blood culture, lactic acid, CRP, WBC, ABG, troponins, serum electrolytes, etc). Please include units and reference ranges when applicable. Please leave query open until answered.' (Site from Safety).	(b) (4), (b) (6)	22 Sep 2020 15:52:37

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Audit	User	Time (GMT)
User closed query 'PV Query: Please provide any relevant laboratory/diagnostic test results (i.e. urinalysis, urine/blood culture, lactic acid, CRP, WBC, ABG, troponins, serum electrolytes, etc). Please include units and reference ranges when applicable.' (Site from Safety).	(b) (4), (b) (6)	22 Sep 2020 15:52:37
Query 'PV Query: Please provide any relevant laboratory/diagnostic test results (i.e. urinalysis, urine/blood culture, lactic acid, CRP, WBC, ABG, troponins, serum electrolytes, etc). Please include units and reference ranges when applicable.'	Mariete Rendon (b) (4)	21 Sep 2020 19:00:38
answered with 'Unknown at this time. Pending Medical records.' (Site from Safety).	(b) (4)	
User opened query 'PV Query: Please confirm if percutaneous drain was a one-time drain, or if drainage catheter was left in place upon discharge.' (Site from Safety).	(b) (4), (b) (6)	17 Sep 2020 15:01:12
User opened query 'PV Query: Please provide initial signs and symptoms experienced by the subject.' (Site from Safety).	(b) (4), (b) (6)	17 Sep 2020 15:00:52
User opened query 'PV Query: Please provide any relevant laboratory/diagnostic test results (i.e. urinalysis, urine/blood culture, lactic acid, CRP, WBC, ABG, troponins, serum electrolytes, etc). Please include units and reference ranges when applicable.' (Site from Safety).	(b) (4), (b) (6)	17 Sep 2020 14:59:57

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Form: Adverse Events (2)

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT EMERGENCY CONTACT REPORTED THAT THE PATIENT WAS HOSPITALIZED ON SAME DATE 31AUG2020 IN ICU WITH ACUTE EXACERBATION OF NEPHROLITHIASIS AND THAT SYMPTOMS WERE GETTING WORSE. SUBJECT WAS TRANSFERED TO HOSPITAL VIA RESCUE. RECORDS WILL BE REQUESTED AS SOON AS PATIENT IS DISCHARGED. 09SEP2020-Discharged records received by email from subject. She has Pyelonephritis confirmed by nephrostogram antegrade urography on 01SEP2020 (at admission). This event Lead to a septic shock, elevated tropinonins ans septic acidosis beggining ICU admission for IV ABs, IV Fluids, and percutaneous drainage. Still waiting for records from hospital for details. Recovering at home with nursing care to complete ABs IV treatment and drainage/ wound care will follow up. Discussed with PI will discharge IP treatment .' reason for change: Data Entry Error	Mariete Rendon (b) (4)	09 Sep 2020 16:20:21
User entered 'Subject emergency contact reported that the patient was hospitalized on same date 31AUG2020 in ICU with acute exacerbation of nephrolithiasis and that symptoms were getting worse. subject was transfered to hospital via rescue. Records will be requested as soon as patient is discharged.'	Mariete Rendon (b) (4)	02 Sep 2020 18:25:17

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Folder: Adverse Events

Form: Adverse Events (2)

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Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
User entered 'I'	System	02 Sep 2020 18:25:17

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Folder: Adverse Events

Form: Adverse Events (2)

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Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	18 Feb 2021 21:20:58
User entered '0'	System	30 Jan 2021 15:50:21
User entered '1'	System	30 Jan 2021 15:49:41
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
User entered '0'	System	09 Sep 2020 16:20:21
User entered '1'	System	02 Sep 2020 18:25:17

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Folder: Adverse Events

Form: Adverse Events (2)

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
User entered 'I'	System	02 Sep 2020 18:25:17

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Folder: Adverse Events

Form: Adverse Events (3)

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[AEID](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:07
User entered 'USA-US118-2020-mRNA-1273-P301000001'	(b) (4), (b) (6)	11 Sep 2020 00:09:14

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Folder: Adverse Events

Form: Adverse Events (3)

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[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Sepsis, bacteraemia, viraemia and fungaemia NEC, PT: Septic shock, LLT: Septic shock - version MedDRA\23.0.	Coder Import (b) (4)	19 Nov 2020 01:22:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	19 Nov 2020 01:22:54
Data point term sent to Coder	System	19 Nov 2020 01:22:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
Data point term sent to Coder	System	12 Nov 2020 17:26:44
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Sepsis, bacteraemia, viraemia and fungaemia NEC, PT: Septic shock, LLT: Septic shock - version MedDRA\23.0.	Coder Import (b) (4)	06 Nov 2020 02:39:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	06 Nov 2020 02:39:37
Data point term sent to Coder	System	06 Nov 2020 02:38:24
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
Data point term sent to Coder	System	30 Oct 2020 19:48:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User closed query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Sep 2020 18:10:45
Query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' answered with 'Unknown at this time. Pending medical records.' (Site from Safety).	Mariete Rendon (b) (4)	24 Sep 2020 18:53:50

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EAB) (1725)

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Form: Adverse Events (3)

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[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	17 Sep 2020 15:02:00
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Sepsis, bacteraemia, viraemia and fungaemia NEC, PT: Septic shock, LLT: Septic shock - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 18:39:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 18:39:56
Data point term sent to Coder	System	09 Sep 2020 18:39:35
User entered 'SEPTIC SHOCK'	Mariete Rendon (b) (4) (b) (4)	09 Sep 2020 18:39:04

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:17:07
DataPoint Un-verified.	Jessie Downs (b) (4)	18 Feb 2021 21:22:01
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4)	18 Feb 2021 21:22:01
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered 'No (N)'	Mariete Rendon (b) (4)	09 Sep 2020 18:39:04

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	09 Sep 2020 18:39:04

US3172038

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:34:29

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	09 Sep 2020 18:39:04

US3172038

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:34:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered '1 Sep 2020'	Mariete Rendon (b) (4) (b) (4)	09 Sep 2020 18:39:04

US3172038

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:34:29

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered empty.	Mariete Rendon (b) (4) (b) (4)	09 Sep 2020 18:39:04

US3172038

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:34:29

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
User entered empty.	System	09 Sep 2020 18:39:04

US3172038

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:34:29

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	09 Sep 2020 18:39:04

US3172038

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:34:29

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered '3 Sep 2020'	Mariete Rendon (b) (4) (b) (4)	09 Sep 2020 18:39:04

US3172038

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:34:29

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered empty.	Mariete Rendon (b) (4) (b) (4)	09 Sep 2020 18:39:04

US3172038

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:34:29

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' canceled (Site from Safety).	(b) (4), (b) (6)	29 Oct 2020 22:33:33
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from Safety).	(b) (4), (b) (6)	17 Sep 2020 15:02:46
User entered empty.	System	09 Sep 2020 18:39:04

US3172038

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:34:29

[Severity](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered 'Grade 4 (Grade 4)'	Mariete Rendon (b) (4) (b) (4)	09 Sep 2020 18:39:04

US3172038

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:34:29

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	09 Sep 2020 18:39:04

US3172038

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:34:29

[Death](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered '0'	Mariete Rendon (b) (4) (b) (4)	09 Sep 2020 18:39:04

US3172038

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:34:29

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered 'I'	Mariete Rendon (b) (4) (b) (4)	09 Sep 2020 18:39:04

US3172038

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:34:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered 'I'	Mariete Rendon (b) (4) (b) (4)	09 Sep 2020 18:39:04

US3172038

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:34:29

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered '1 Sep 2020'	Mariete Rendon (b) (4) (b) (4)	09 Sep 2020 18:39:04

US3172038

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:34:29

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered '4 Sep 2020'	Mariete Rendon (b) (4) (b) (4)	09 Sep 2020 18:39:04

US3172038

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:34:29

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User closed query 'PV Query: Please confirm if vital signs remained stable during ICU admission. If not, please provide abnormal vital signs, along with treatment.' (Site from Safety).	(b) (4), (b) (6)	25 Sep 2020 18:10:57
Query 'PV Query: Please confirm if vital signs remained stable during ICU admission. If not, please provide abnormal vital signs, along with treatment.' answered with 'Unknown at this time. Pending medical records.' (Site from Safety).	Mariete Rendon (b) (4)	24 Sep 2020 18:53:55
User opened query 'PV Query: Please confirm if vital signs remained stable during ICU admission. If not, please provide abnormal vital signs, along with treatment.' (Site from Safety).	(b) (4), (b) (6)	17 Sep 2020 15:03:24
User entered 'Yes (Y)'	Mariete Rendon (b) (4)	09 Sep 2020 18:39:04

US3172038

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:34:29

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered '3'	Mariete Rendon (b) (4) (b) (4)	09 Sep 2020 18:39:04

US3172038

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:34:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered '0'	Mariete Rendon (b) (4) (b) (4)	09 Sep 2020 18:39:04

US3172038

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:34:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered '0'	Mariete Rendon (b) (4) (b) (4)	09 Sep 2020 18:39:04

US3172038

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:34:29

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered '0'	Mariete Rendon (b) (4) (b) (4)	09 Sep 2020 18:39:04

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:34:29

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
Query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	25 Sep 2020 13:13:42
User opened query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	09 Sep 2020 18:39:04
User entered 'Not Related (NOT RELATED)'	Mariete Rendon (b) (4) (b) (4)	09 Sep 2020 18:39:04

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:34:29

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered 'Not Related (NOT RELATED)'	Mariete Rendon (b) (4) (b) (4)	09 Sep 2020 18:39:04

US3172038

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:34:29

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User closed query 'Per CDM: "Action taken with investigational product is Investigational Product Withdrawn". However Exposure form and Dosing Discontinuation form is not updated under End of study folder. Please review and update the data accordingly. Thank you' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 14:48:32
User closed query 'PV query: How many days after second dose of mRNA-1273 or placebo did the patient experienced the SAE?' (Site from Safety).	(b) (4), (b) (6)	25 Sep 2020 19:29:37
Query 'PV query: How many days after second dose of mRNA-1273 or placebo did the patient experienced the SAE?' answered with '2nd dose was ND subject was at the hospital recovering' (Site from Safety).	Mariete Rendon (b) (4)	25 Sep 2020 16:26:52
Query 'Per CDM: "Action taken with investigational product is Investigational Product Withdrawn". However Exposure form and Dosing Discontinuation form is not updated under End of study folder. Please review and update the data accordingly. Thank you' answered with 'Data updated' (Site from DM).	Mariete Rendon (b) (4)	25 Sep 2020 16:26:27
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Mariete Rendon (b) (4)	25 Sep 2020 16:26:19
User opened query 'PV query: How many days after second dose of mRNA-1273 or placebo did the patient experienced the SAE?' (Site from Safety).	(b) (4), (b) (6)	17 Sep 2020 15:02:13
User opened query 'Per CDM: "Action taken with investigational product is Investigational Product Withdrawn". However Exposure form and Dosing Discontinuation form is not updated under End of study folder. Please review and update the data accordingly. Thank you' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 02:31:39

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:34:29

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	Mariete Rendon (b) (4) (b) (4)	09 Sep 2020 18:39:04

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:34:29

None

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered '0'	Mariete Rendon (b) (4) (b) (4)	09 Sep 2020 18:39:04

US3172038

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:34:29

[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	21 Nov 2020 13:24:15
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:12:34
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 19:42:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'See conmed log' (Site from DM).	Mariete Rendon (b) (4) (b) (4)	27 Oct 2020 20:22:17
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 03:44:51
User closed query 'PV Query: Please provide treatment given for the event. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).' (Site from Safety).	(b) (4), (b) (6)	25 Sep 2020 18:12:27

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:34:29

[Concomitant Medication](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide treatment given for the event. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).' answered with 'Unknown at this time. Pending medical records.' (Site from Safety).	Mariete Rendon (b) (4)	24 Sep 2020 18:54:09
User opened query 'PV Query: Please provide treatment given for the event. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).' (Site from Safety).	(b) (4)	
User entered '1'	(b) (4), (b) (6)	17 Sep 2020 15:03:05
	Mariete Rendon (b) (4)	09 Sep 2020 18:39:04
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:34:29

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR - RQ: Site's response noted. However, please confirm what is the procedure performed to manage SEPTIC SHOCK. Note that the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 08:32:52
Query 'Per DM CLR - RQ: Site's response noted. However, please confirm what is the procedure performed to manage SEPTIC SHOCK. Note that the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken.' answered with 'Pending medical records.' (Site from DM).	Jessie Downs (b) (4) (b) (4)	18 Feb 2021 21:22:09
User opened query 'Per DM CLR - RQ: Site's response noted. However, please confirm what is the procedure performed to manage SEPTIC SHOCK. Note that the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 05:21:57
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	21 Nov 2020 13:24:18
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:12:39
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:34:29

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 19:42:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
Query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' answered with 'see conmed procedure' (Site from DM).	Mariete Rendon (b) (4) (b) (4)	27 Oct 2020 20:22:31
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 03:44:57
User entered 'I'	Mariete Rendon (b) (4) (b) (4)	09 Sep 2020 18:39:04

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Folder: Adverse Events

Form: Adverse Events (3)

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[Outcome](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Mariete Rendon (b) (4) (b) (4)	09 Sep 2020 18:39:04

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered empty.	Mariete Rendon (b) (4) (b) (4)	09 Sep 2020 18:39:04

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Folder: Adverse Events

Form: Adverse Events (3)

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[Narrative](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User closed query 'Per DM CLR: SAE Narrative contains medications and procedures. Please make sure that these information are recorded in their respective eCRFs. Otherwise, clarify the inconsistencies.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 16:18:40
User closed query 'PV Query: Please provide initial signs and symptoms experienced by the subject.' (Site from Safety).	(b) (4), (b) (6)	30 Sep 2020 12:29:11
Query 'Per DM CLR: SAE Narrative contains medications and procedures. Please make sure that these information are recorded in their respective eCRFs. Otherwise, clarify the inconsistencies.' answered with 'Waiting on medical records' (Site from DM).	Jessie Downs (b) (4) (b) (4)	29 Sep 2020 21:45:27
User opened query 'Per DM CLR: SAE Narrative contains medications and procedures. Please make sure that these information are recorded in their respective eCRFs. Otherwise, clarify the inconsistencies.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 02:26:32
Query 'PV Query: Please provide initial signs and symptoms experienced by the subject.' answered with 'Information pending' (Site from Safety).	Mariete Rendon (b) (4) (b) (4)	28 Sep 2020 17:49:53
User closed query 'PV Query: Please provide any relevant laboratory/diagnostic test results (i.e. urinalysis, urine/blood culture, lactic acid, CRP, WBC, ABG, troponins, serum electrolytes, etc). Please include units and reference ranges when applicable.' (Site from Safety).	(b) (4), (b) (6)	25 Sep 2020 18:12:16

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Folder: Adverse Events

Form: Adverse Events (3)

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory/diagnostic test results (i.e. urinalysis, urine/blood culture, lactic acid, CRP, WBC, ABG, troponins, serum electrolytes, etc). Please include units and reference ranges when applicable.'	Mariete Rendon (b) (4)	24 Sep 2020 18:54:29
answered with 'Unknown at this time. Pending medical records.' (Site from Safety).	(b) (4)	
User opened query 'PV Query: Please provide initial signs and symptoms experienced by the subject.' (Site from Safety).	(b) (4), (b) (6)	17 Sep 2020 15:03:13
User opened query 'PV Query: Please provide any relevant laboratory/diagnostic test results (i.e. urinalysis, urine/blood culture, lactic acid, CRP, WBC, ABG, troponins, serum electrolytes, etc). Please include units and reference ranges when applicable.'	(b) (4), (b) (6)	17 Sep 2020 15:02:25
(Site from Safety).		
User entered 'SEPTIC SHOCK, SECONDARY TO AN ACUTE PYELONEPHRITIS REQUIRING ICU ADMISSION, IV FLUIDS, IV ABS PERCUTANEOUS DRAINAGE AND OTHER ACUTE MEASURES. PENDING MEDICAL RECORDS TO COMPLETE INFO.DISCUSSED WITH PI WILL DISCHARGE IP TREATMENT.'	Mariete Rendon (b) (4)	09 Sep 2020 18:39:04
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:34:29

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
User entered 'I'	System	09 Sep 2020 18:39:04

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:34:29

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	18 Feb 2021 21:22:01
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
User entered '0'	System	09 Sep 2020 18:39:04

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:34:29

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
User entered 'I'	System	09 Sep 2020 18:39:04

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:34:29

[AEID](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:34:29

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:23:49
User closed query 'AE # 2 and # 4 are the same diagnosis. If not duplicates, then one of the dates of resolution needs to be corrected. AE # 2 onset 01Sep, resolved 26Sep. AE # 4 onset 22Sep, resolved 26Sep. The date resolved for AE # 2 would have to be before the start of AE # 4 for them not to be duplicates. However, the name of this AE # 4 "unresolved..." means it is the same event as AE # 2. We can discuss on site at my next visit.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 18:18:40
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Urinary tract infections, PT: Pyelonephritis, LLT: Pyelonephritis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Apr 2021 15:15:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Apr 2021 15:15:49
Data point term sent to Coder	System	09 Apr 2021 18:52:21
Query 'AE # 2 and # 4 are the same diagnosis. If not duplicates, then one of the dates of resolution needs to be corrected. AE # 2 onset 01Sep, resolved 26Sep. AE # 4 onset 22Sep, resolved 26Sep. The date resolved for AE # 2 would have to be before the start of AE # 4 for them not to be duplicates. However, the name of this AE # 4 "unresolved..." means it is the same event as AE # 2. We can discuss on site at my next visit.' answered by data change (Site from CRA).	System	09 Apr 2021 18:51:34
Coding entries removed.	Mariete Rendon (b) (4) (b) (4)	09 Apr 2021 18:51:34
User entered 'update for original SAE. second hospitalization due to UNRESOLVED RIGHT KIDNEY PYELONEPHRITIS' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	09 Apr 2021 18:51:34
User closed query 'Per DM CLR: Please review the dates of this AE as it overlap with AE #2. Please reconcile and update so there is no overlap or delete duplicate record as applicable. Otherwise, clarify. Please also note that AE downgrades are not recorded as a separate AE.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 06:29:43

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:34:29

[Adverse event](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please review the dates of this AE as it overlap with AE #2. Please reconcile and update so there is no overlap or delete duplicate record as applicable. Otherwise, clarify. Please also note that AE downgrades are not recorded as a separate AE.' answered with 'Second hospitalization related to main SAE.' (Site from DM).	Jessie Downs (b) (4)	19 Mar 2021 19:34:30
User opened query 'AE # 2 and # 4 are the same diagnosis. If not duplicates, then one of the dates of resolution needs to be corrected. AE # 2 onset 01Sep, resolved 26Sep. AE # 4 onset 22Sep, resolved 26Sep. The date resolved for AE # 2 would have to be before the start of AE # 4 for them not to be duplicates. However, the name of this AE # 4 "unresolved..." means it is the same event as AE # 2. We can discuss on site at my next visit.' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 21:57:20
User closed query 'Isn't this a duplicate of SAE # 2?' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 21:57:20
User opened query 'Per DM CLR: Please review the dates of this AE as it overlap with AE #2. Please reconcile and update so there is no overlap or delete duplicate record as applicable. Otherwise, clarify. Please also note that AE downgrades are not recorded as a separate AE.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 22:31:31
Query 'Isn't this a duplicate of SAE # 2?' answered with 'Not a duplicate' (Site from CRA).	Jessie Downs (b) (4)	30 Jan 2021 15:50:56
User closed query 'Per MM: Please update event term to reflect etiology/medical diagnosis if known (shock?)' (Site from DM).	(b) (4), (b) (6)	21 Nov 2020 13:24:44
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Urinary tract infections, PT: Pyelonephritis, LLT: Pyelonephritis - version MedDRA\23.0.	Coder Import (b) (4)	19 Nov 2020 01:22:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	19 Nov 2020 01:22:53
Data point term sent to Coder	System	19 Nov 2020 01:22:09
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
Data point term sent to Coder	System	12 Nov 2020 17:26:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25

PRODUCTION RELEASE (v12.003
EAB) (1725)

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[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'Isn't this a duplicate of SAE # 2?' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 17:20:49
User closed query 'This is a symptom of the pyelonephritis, not a diagnosis. Consider removing.' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 17:20:49
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Urinary tract infections, PT: Pyelonephritis, LLT: Pyelonephritis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 12:07:31
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 12:07:31
Data point term sent to Coder	System	06 Nov 2020 21:26:19
Query 'This is a symptom of the pyelonephritis, not a diagnosis. Consider removing.' answered with 'Data updated' (Site from CRA).	Mariete Rendon (b) (4) (b) (4)	06 Nov 2020 21:25:34
Coding entries removed.	Mariete Rendon (b) (4) (b) (4)	06 Nov 2020 21:25:27
User entered 'unresolved right kidney pyelonephritis' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	06 Nov 2020 21:25:27
User coded data point as SOC: General disorders and administration site conditions, HLGT: Body temperature conditions, HLT: Febrile disorders, PT: Pyrexia, LLT: Fever - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 02:39:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 02:39:38
Data point term sent to Coder	System	06 Nov 2020 02:38:24
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
Data point term sent to Coder	System	30 Oct 2020 19:48:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 19:44:17
User opened query 'This is a symptom of the pyelonephritis, not a diagnosis. Consider removing.' (Site from CRA).	(b) (4), (b) (6)	30 Oct 2020 19:43:56
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12

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[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: General disorders and administration site conditions, HLGT: Body temperature conditions, HLT: Febrile disorders, PT: Pyrexia, LLT: Fever - version MedDRA\\23.0.	Coder Import (b) (4)	27 Oct 2020 22:59:30
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	27 Oct 2020 22:59:30
Query 'Per MM: Please update event term to reflect etiology/medical diagnosis if known (shock?)' answered with 'related to unresolved right kidney pyelonephritis' (Site from DM).	Mariete Rendon (b) (4)	27 Oct 2020 20:18:28
Data point term sent to Coder	System	27 Oct 2020 20:17:43
Coding entries removed.	Mariete Rendon (b) (4)	27 Oct 2020 20:17:25
User entered 'RECCURENT FEVER' reason for change: Data Entry Error	Mariete Rendon (b) (4)	27 Oct 2020 20:17:25
User opened query 'Per MM: Please update event term to reflect etiology/medical diagnosis if known (shock?)' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 13:43:49
User coded data point as SOC: General disorders and administration site conditions, HLGT: Body temperature conditions, HLT: Febrile disorders, PT: Pyrexia, LLT: Fever - version MedDRA\\23.0.	Coder Import (b) (4)	26 Sep 2020 09:23:39
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	26 Sep 2020 09:23:39
Data point term sent to Coder	System	25 Sep 2020 17:56:33
User entered 'Reccurent persistent fever'	Mariete Rendon (b) (4)	25 Sep 2020 17:55:50

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:23:49
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4)	18 Feb 2021 21:23:38
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 19:44:19
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered 'No (N)'	Mariete Rendon (b) (4)	25 Sep 2020 17:55:50
	(b) (4)	

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Form: Adverse Events (4)

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:23:49
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 19:44:21
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	25 Sep 2020 17:55:50

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:23:49
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 19:44:22
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	25 Sep 2020 17:55:50

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:34:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:23:49
User closed query 'Start date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	04 Dec 2020 21:08:41
User opened query 'Start date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	04 Dec 2020 20:55:19
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 19:44:24
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered '22 Sep 2020'	Mariete Rendon (b) (4) (b) (4)	25 Sep 2020 17:55:50

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Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:34:29

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:23:49
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 19:44:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered empty.	Mariete Rendon (b) (4) (b) (4)	25 Sep 2020 17:55:50

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:34:29

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
User entered empty.	System	25 Sep 2020 17:55:50

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:34:29

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:23:49
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 19:44:28
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered 'No (N)' reason for change: Data Entry Error	Mariete Rendon (b) (4)	27 Oct 2020 20:16:33
User entered 'Yes (Y)'	Mariete Rendon (b) (4)	25 Sep 2020 17:55:50

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:34:29

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:23:49
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 19:44:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered '26 Sep 2020' reason for change: Data Entry Error	Mariete Rendon (b) (4)	27 Oct 2020 20:16:33
User entered empty.	Mariete Rendon (b) (4)	25 Sep 2020 17:55:50

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:34:29

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:23:49
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 19:44:31
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered empty.	Mariete Rendon (b) (4) (b) (4)	25 Sep 2020 17:55:50

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:34:29

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
User entered empty.	System	25 Sep 2020 17:55:50

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:34:29

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:23:49
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 19:44:33
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered 'Grade 3/Severe (Grade 3/Severe)'	Mariete Rendon (b) (4) (b) (4)	25 Sep 2020 17:55:50

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:34:29

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:23:49
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 19:44:34
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	25 Sep 2020 17:55:50

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:34:29

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:23:49
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 19:44:36
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered '0'	Mariete Rendon (b) (4) (b) (4)	25 Sep 2020 17:55:50

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:34:29

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:23:49
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 19:44:37
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered '0'	Mariete Rendon (b) (4) (b) (4)	25 Sep 2020 17:55:50

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Folder: Adverse Events

Form: Adverse Events (4)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:23:49
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 19:44:39
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered '0'	Mariete Rendon (b) (4) (b) (4)	25 Sep 2020 17:55:50

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:34:29

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:23:49
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 19:44:40
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered empty.	Mariete Rendon (b) (4) (b) (4)	25 Sep 2020 17:55:50

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:34:29

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:23:49
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 19:44:42
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered empty.	Mariete Rendon (b) (4) (b) (4)	25 Sep 2020 17:55:50

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Form: Adverse Events (4)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:23:49
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 19:44:44
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered empty.	Mariete Rendon (b) (4) (b) (4)	25 Sep 2020 17:55:50

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:23:49
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 19:44:45
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered empty.	Mariete Rendon (b) (4) (b) (4)	25 Sep 2020 17:55:50

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Folder: Adverse Events

Form: Adverse Events (4)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:23:49
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 19:44:46
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered '0'	Mariete Rendon (b) (4) (b) (4)	25 Sep 2020 17:55:50

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Folder: Adverse Events

Form: Adverse Events (4)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:23:49
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 19:44:48
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered '0'	Mariete Rendon (b) (4) (b) (4)	25 Sep 2020 17:55:50

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:23:49
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 19:44:49
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered '0'	Mariete Rendon (b) (4) (b) (4)	25 Sep 2020 17:55:50

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Form: Adverse Events (4)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:23:49
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 19:44:50
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered 'Not Related (NOT RELATED)'	Mariete Rendon (b) (4) (b) (4)	25 Sep 2020 17:55:50

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Generated On: 09 Jun 2021 15:34:29

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:23:49
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 19:44:52
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered 'Not Related (NOT RELATED)'	Mariete Rendon (b) (4) (b) (4)	25 Sep 2020 17:55:50

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Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:34:29

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:23:49
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 19:44:53
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered 'Not Applicable (NOT APPLICABLE)'	Mariete Rendon (b) (4) (b) (4)	25 Sep 2020 17:55:50

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:34:29

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:23:49
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 19:44:55
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered '0'	Mariete Rendon (b) (4) (b) (4)	25 Sep 2020 17:55:50

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Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:34:29

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:23:49
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	21 Nov 2020 13:24:57
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 19:44:56
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'See conmed log' (Site from DM).	Mariete Rendon (b) (4) (b) (4)	27 Oct 2020 20:18:36
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 03:43:45
User entered 'I'	Mariete Rendon (b) (4) (b) (4)	25 Sep 2020 17:55:50

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:34:29

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:23:49
User closed query 'Per DM CLR re-query: Response noted. However, please consider updating the corresponding conmed procedure when data is available. Kindly leave the query open until the procedure is updated.' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 17:56:35
Query 'Per DM CLR re-query: Response noted. However, please consider updating the corresponding conmed procedure when data is available. Kindly leave the query open until the procedure is updated.' answered with 'Data updated' (Site from DM).	Mariete Rendon (b) (4)	12 Apr 2021 18:34:49
User opened query 'Per DM CLR re-query: Response noted. However, please consider updating the corresponding conmed procedure when data is available. Kindly leave the query open until the procedure is updated.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 08:49:53
User closed query 'Per DM CLR - RQ: Site's response noted. However, please confirm what is the procedure performed to manage PYELONEPHRITIS. Note that the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 08:49:53
Query 'Per DM CLR - RQ: Site's response noted. However, please confirm what is the procedure performed to manage PYELONEPHRITIS. Note that the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken.' answered with 'Pending medical records.' (Site from DM).	Jessie Downs (b) (4)	18 Feb 2021 21:22:56
User opened query 'Per DM CLR - RQ: Site's response noted. However, please confirm what is the procedure performed to manage PYELONEPHRITIS. Note that the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 05:23:37

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Form: Adverse Events (4)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	21 Nov 2020 13:24:59
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 19:44:58
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
Query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' answered with 'Data updated' (Site from DM).	Mariete Rendon (b) (4)	27 Oct 2020 20:21:20
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 03:43:51
User entered 'I'	Mariete Rendon (b) (4)	25 Sep 2020 17:55:50

US3172038

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:34:29

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:23:49
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 19:45:00
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	27 Oct 2020 20:16:33
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Mariete Rendon (b) (4) (b) (4)	25 Sep 2020 17:55:50

US3172038

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:34:29

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:23:49
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 19:45:01
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered empty.	Mariete Rendon (b) (4) (b) (4)	25 Sep 2020 17:55:50

US3172038

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:34:29

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:23:49
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 19:45:03
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered empty.	Mariete Rendon (b) (4) (b) (4)	25 Sep 2020 17:55:50

US3172038

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:34:29

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
User entered '0'	System	25 Sep 2020 17:55:50

US3172038

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:34:29

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	18 Feb 2021 21:23:38
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
User entered 'O'	System	25 Sep 2020 17:55:50

US3172038

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:34:29

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:34:29

[AEID](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29

US3172038

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:34:29

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Renal and urinary disorders, HLGT: Urinary tract signs and symptoms, HLT: Urinary tract signs and symptoms NEC, PT: Renal colic, LLT: Renal colic - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 01:22:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 01:22:53
Data point term sent to Coder	System	19 Nov 2020 01:22:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
Data point term sent to Coder	System	12 Nov 2020 17:26:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
User coded data point as SOC: Renal and urinary disorders, HLGT: Urinary tract signs and symptoms, HLT: Urinary tract signs and symptoms NEC, PT: Renal colic, LLT: Renal colic - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 02:39:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 02:39:34
Data point term sent to Coder	System	06 Nov 2020 02:38:24
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
Data point term sent to Coder	System	30 Oct 2020 19:48:55
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:45:11
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 19:45:08
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User coded data point as SOC: Renal and urinary disorders, HLGT: Urinary tract signs and symptoms, HLT: Urinary tract signs and symptoms NEC, PT: Renal colic, LLT: Renal colic - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Oct 2020 22:16:25
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Oct 2020 22:16:25
Data point term sent to Coder	System	27 Oct 2020 20:14:35
Coding entries removed.	Mariete Rendon (b) (4) (b) (4)	27 Oct 2020 20:14:04

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:34:29

[Adverse event](#)

Audit	User	Time (GMT)
User entered 'acute RENAL COLIC' reason for change: Data Entry Error	Mariete Rendon (b) (4)	27 Oct 2020 20:14:04
User coded data point as SOC: Renal and urinary disorders, HLGT: Urinary tract signs and symptoms, HLT: Urinary tract signs and symptoms NEC, PT: Renal colic, LLT: Renal colic - version MedDRA\\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Sep 2020 18:00:47
Data point term sent to Coder	(b) (4)	
User entered 'Renal Colic'	System	25 Sep 2020 17:59:37
	Mariete Rendon (b) (4)	25 Sep 2020 17:58:55
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:34:29

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 21:58:20
User closed query 'Medically attended AEs are defined as any AEs that lead to an unscheduled visit to a healthcare practitioner.' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 21:58:17
Query 'Medically attended AEs are defined as any AEs that lead to an unscheduled visit to a healthcare practitioner.' answered with 'Data was updated.' (Site from CRA).	Jessie Downs (b) (4) (b) (4)	30 Jan 2021 15:52:06
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	30 Jan 2021 15:51:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
User opened query 'Medically attended AEs are defined as any AEs that lead to an unscheduled visit to a healthcare practitioner.' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 17:22:27
User closed query 'Should this be yes since subject attended the ED?' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 17:22:27
Query 'Should this be yes since subject attended the ED?' answered with 'SAE involves (MAAE) please advise if we can choose more than one option?' (Site from CRA).	Mariete Rendon (b) (4) (b) (4)	06 Nov 2020 21:25:55
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
User opened query 'Should this be yes since subject attended the ED?' (Site from CRA).	(b) (4), (b) (6)	30 Oct 2020 19:46:00
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 19:45:36
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:45:13
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 19:45:10
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	25 Sep 2020 17:58:55

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:34:29

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	25 Sep 2020 17:58:55

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:34:29

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	25 Sep 2020 17:58:55

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:34:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered '29 Aug 2020' reason for change: Data Entry Error	Mariete Rendon (b) (4)	21 Oct 2020 22:29:05
User entered '30 Aug 2020'	Mariete Rendon (b) (4)	25 Sep 2020 17:58:55

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:34:29

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered empty.	Mariete Rendon (b) (4) (b) (4)	25 Sep 2020 17:58:55

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:34:29

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
User entered empty.	System	25 Sep 2020 17:58:55

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:34:29

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	25 Sep 2020 17:58:55

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:34:29

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered '30 Aug 2020' reason for change: Data Entry Error	Mariete Rendon (b) (4)	21 Oct 2020 22:29:05
User entered '31 Aug 2020'	Mariete Rendon (b) (4)	25 Sep 2020 17:58:55

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:34:29

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered empty.	Mariete Rendon (b) (4) (b) (4)	25 Sep 2020 17:58:55

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:34:29

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
User entered empty.	System	25 Sep 2020 17:58:55

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:34:29

[Severity](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered 'Grade 3/Severe (Grade 3/Severe)'	Mariete Rendon (b) (4) (b) (4)	25 Sep 2020 17:58:55

US3172038

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:34:29

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	25 Sep 2020 17:58:55

US3172038

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:34:29

[Death](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered '0'	Mariete Rendon (b) (4) (b) (4)	25 Sep 2020 17:58:55

US3172038

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:34:29

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered '0'	Mariete Rendon (b) (4) (b) (4)	25 Sep 2020 17:58:55

US3172038

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:34:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered '0'	Mariete Rendon (b) (4) (b) (4)	25 Sep 2020 17:58:55

US3172038

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:34:29

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered empty.	Mariete Rendon (b) (4) (b) (4)	25 Sep 2020 17:58:55

US3172038

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:34:29

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered empty.	Mariete Rendon (b) (4) (b) (4)	25 Sep 2020 17:58:55

US3172038

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:34:29

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered empty.	Mariete Rendon (b) (4) (b) (4)	25 Sep 2020 17:58:55

US3172038

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:34:29

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered empty.	Mariete Rendon (b) (4) (b) (4)	25 Sep 2020 17:58:55

US3172038

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:34:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered '0'	Mariete Rendon (b) (4) (b) (4)	25 Sep 2020 17:58:55

US3172038

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:34:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered '0'	Mariete Rendon (b) (4) (b) (4)	25 Sep 2020 17:58:55

US3172038

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:34:29

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered '0'	Mariete Rendon (b) (4) (b) (4)	25 Sep 2020 17:58:55

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:34:29

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered 'Not Related (NOT RELATED)'	Mariete Rendon (b) (4) (b) (4)	25 Sep 2020 17:58:55

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:34:29

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered 'Not Related (NOT RELATED)'	Mariete Rendon (b) (4) (b) (4)	25 Sep 2020 17:58:55

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:34:29

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered 'Not Applicable (NOT APPLICABLE)'	Mariete Rendon (b) (4) (b) (4)	25 Sep 2020 17:58:55

US3172038

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:34:29

None

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered 'I'	Mariete Rendon (b) (4) (b) (4)	25 Sep 2020 17:58:55

US3172038

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:34:29

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered '0'	Mariete Rendon (b) (4) (b) (4)	25 Sep 2020 17:58:55

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:34:29

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered '0'	Mariete Rendon (b) (4) (b) (4)	25 Sep 2020 17:58:55

US3172038

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:34:29

[Outcome](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Mariete Rendon (b) (4) (b) (4)	25 Sep 2020 17:58:55

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:34:29

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered empty.	Mariete Rendon (b) (4) (b) (4)	25 Sep 2020 17:58:55

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:34:29

[Narrative](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered empty.	Mariete Rendon (b) (4) (b) (4)	25 Sep 2020 17:58:55

US3172038

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:34:29

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
User entered '0'	System	25 Sep 2020 17:58:55

US3172038

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:34:29

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	30 Jan 2021 15:51:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
User entered '0'	System	25 Sep 2020 17:58:55

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:34:29

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:34:29

[AEID](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 19:15:24
User entered 'USA-US118-2020-mRNA-1273-P301000001'	(b) (4), (b) (6)	22 Oct 2020 19:15:07

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:34:29

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Respiratory failures (excl neonatal), PT: Acute respiratory failure, LLT: Acute respiratory failure - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Apr 2021 18:20:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Apr 2021 18:20:50
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Respiratory failures (excl neonatal), PT: Respiratory failure, LLT: Hypoxic respiratory failure - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Mar 2021 17:11:56
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Mar 2021 17:11:56
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Respiratory failures (excl neonatal), PT: Acute respiratory failure, LLT: Acute respiratory failure - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 01:22:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 01:22:56
Data point term sent to Coder	System	19 Nov 2020 01:22:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
Data point term sent to Coder	System	12 Nov 2020 17:26:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Respiratory failures (excl neonatal), PT: Acute respiratory failure, LLT: Acute respiratory failure - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 02:39:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 02:39:34
Data point term sent to Coder	System	06 Nov 2020 02:38:24
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
Data point term sent to Coder	System	30 Oct 2020 19:48:55
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:34:29

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Respiratory failures (excl neonatal), PT: Acute respiratory failure, LLT: Acute respiratory failure - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 23:33:36
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 23:33:36
Data point term sent to Coder	System	21 Oct 2020 22:33:51
User entered 'ACUTE HYPOXEMIC RESPIRATORY FAILURE'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 22:33:43

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:34:29

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 22:33:43

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:34:29

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 22:33:43

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:34:29

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 22:33:43

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:34:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered '1 Sep 2020'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 22:33:43

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:34:29

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 22:33:43

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:34:29

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
User entered empty.	System	21 Oct 2020 22:33:43

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:34:29

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 22:33:43

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:34:29

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered '3 Sep 2020'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 22:33:43

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:34:29

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 22:33:43

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:34:29

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
User entered empty.	System	21 Oct 2020 22:33:43

US3172038

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:34:29

[Severity](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	Mariete Rendon (b) (4)	22 Oct 2020 18:11:47
User entered 'Grade 3/Severe (Grade 3/Severe)'	Mariete Rendon (b) (4)	21 Oct 2020 22:33:43

US3172038

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:34:29

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 22:33:43

US3172038

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:34:29

[Death](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered '0'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 22:33:43

US3172038

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:34:29

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered 'I'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 22:33:43

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:34:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered 'I'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 22:33:43

US3172038

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:34:29

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered '1 Sep 2020'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 22:33:43

US3172038

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:34:29

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered '4 Sep 2020'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 22:33:43

US3172038

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:34:29

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 22:33:43

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:34:29

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered '3'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 22:33:43

US3172038

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:34:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered '0'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 22:33:43

US3172038

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:34:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered '0'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 22:33:43

US3172038

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:34:29

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered '0'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 22:33:43

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:34:29

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered 'Not Related (NOT RELATED)'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 22:33:43

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:34:29

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered 'Not Related (NOT RELATED)'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 22:33:43

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:34:29

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered 'Not Applicable (NOT APPLICABLE)'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 22:33:43

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:34:29

None

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered '0'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 22:33:43

US3172038

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:34:29

[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 04:01:19
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'Medication is added in concomitant log.' (Site from DM).	Jessie Downs (b) (4) (b) (4)	30 Jan 2021 15:52:31
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 05:23:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered '1'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 22:33:43

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:34:29

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' canceled (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 05:24:29
User opened query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 13:59:42
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered 'I'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 22:33:43

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:34:29

[Outcome](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 22:33:43

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:34:29

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 22:33:43

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:34:29

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide any relevant laboratory/diagnostic test results (i.e. urinalysis, urine/blood culture, lactic acid, CRP, WBC, ABG, troponins, serum electrolytes, etc). Please include units and reference ranges when applicable. Please leave query open until answered.' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 15:47:38
Query 'PV Query: Please provide any relevant laboratory/diagnostic test results (i.e. urinalysis, urine/blood culture, lactic acid, CRP, WBC, ABG, troponins, serum electrolytes, etc). Please include units and reference ranges when applicable. Please leave query open until answered.' answered with 'pending medical records. ' (Site from Safety). DataPoint Verified.	Jessie Downs (b) (4)	25 Feb 2021 20:12:24
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 18:19:24
User closed query 'Per DM CLR: Narrative suggest that subject had INTUBATION. However, this is not recorded as Concomittant Procedure. Please review and add all pertinent information in their respective eCRF as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 19:35:05
Query 'Per DM CLR: Narrative suggest that subject had INTUBATION. However, this is not recorded as Concomittant Procedure. Please review and add all pertinent information in their respective eCRF as appropriate. Otherwise, clarify.' answered with 'Intubated added to conmed procedure page as per query request.' (Site from DM).	Mariete Rendon (b) (4)	05 Jan 2021 21:02:36
User opened query 'Per DM CLR: Narrative suggest that subject had INTUBATION. However, this is not recorded as Concomittant Procedure. Please review and add all pertinent information in their respective eCRF as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 13:59:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25

US3172038

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:34:29

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:25:55
User entered 'INTUBATED IN ICU ON 01SEP2020-EXTUBATED' reason for change: Data Entry Error	Mariete Rendon (b) (4)	06 Nov 2020 21:26:18
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 19:47:39
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User opened query 'PV Query: Please provide any relevant laboratory/diagnostic test results (i.e. urinalysis, urine/blood culture, lactic acid, CRP, WBC, ABG, troponins, serum electrolytes, etc). Please include units and reference ranges when applicable. Please leave query open until answered.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 13:58:25
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	21 Oct 2020 22:34:25
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	21 Oct 2020 22:34:25
User entered 'INCUBATED IN icu ON 01sep2020-EXTUBATED' reason for change: Data Entry Error	Mariete Rendon (b) (4)	21 Oct 2020 22:34:25
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	21 Oct 2020 22:33:43
User entered empty.	Mariete Rendon (b) (4)	21 Oct 2020 22:33:43

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:34:29

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
User entered 'I'	System	21 Oct 2020 22:33:43

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:34:29

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
User entered 'I'	System	21 Oct 2020 22:33:43

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:34:29

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
User entered 'I'	System	21 Oct 2020 22:33:43

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:34:29

[AEID](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 19:16:54
User entered 'USA-US118-2020-mRNA-1273-P301000001'	(b) (4), (b) (6)	22 Oct 2020 19:16:42

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Folder: Adverse Events

Form: Adverse Events (7)

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[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Acid-base disorders, HLT: Metabolic acidoses (excl diabetic acidoses), PT: Metabolic acidosis, LLT: Metabolic acidosis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 06:36:55
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 06:36:55
Data point term sent to Coder	System	19 Nov 2020 01:22:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
Data point term sent to Coder	System	12 Nov 2020 17:26:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
Data point term sent to Coder	System	06 Nov 2020 02:38:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
Data point term sent to Coder	System	30 Oct 2020 19:48:56
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
Data point term sent to Coder	System	22 Oct 2020 12:06:53
User closed query 'DM-Coding: The verbatim term appears to be incomplete. Please update the condition/event being reported, alternatively provide more information. ' (Site from System).	System	22 Oct 2020 12:06:14
Query 'DM-Coding: The verbatim term appears to be incomplete. Please update the condition/event being reported, alternatively provide more information. ' answered with 'Term updated' (Site from System).	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:06:14
Data point term sent to Coder	System	22 Oct 2020 12:05:52
User entered 'PROFOUND metabolic acidosis' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:05:27
User opened query 'DM-Coding: The verbatim term appears to be incomplete. Please update the condition/event being reported, alternatively provide more information. ' (Site from System).	Coder Import (b) (4) (b) (4)	22 Oct 2020 08:39:23
Data point term sent to Coder	System	21 Oct 2020 22:35:53
User entered 'PROFOUND'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 22:35:34

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:34:29

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 22:35:34

US3172038

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:34:29

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 22:35:34

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Folder: Adverse Events

Form: Adverse Events (7)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 22:35:34

US3172038

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:34:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered '1 Sep 2020'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 22:35:34

US3172038

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:34:29

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 22:35:34

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:34:29

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
User entered empty.	System	21 Oct 2020 22:35:34

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:34:29

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 22:35:34

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:34:29

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered '3 Sep 2020'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 22:35:34

US3172038

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:34:29

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 22:35:34

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:34:29

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
User entered empty.	System	21 Oct 2020 22:35:34

US3172038

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:34:29

[Severity](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	Mariete Rendon (b) (4)	22 Oct 2020 18:11:32
User entered 'Grade 3/Severe (Grade 3/Severe)'	Mariete Rendon (b) (4)	21 Oct 2020 22:35:34

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:34:29

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 22:35:34

US3172038

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:34:29

[Death](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered '0'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 22:35:34

US3172038

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:34:29

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered 'I'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 22:35:34

US3172038

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:34:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered 'I'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 22:35:34

US3172038

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:34:29

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered '1 Sep 2020'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 22:35:34

US3172038

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:34:29

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered '4 Sep 2020'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 22:35:34

US3172038

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:34:29

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 22:35:34

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Folder: Adverse Events

Form: Adverse Events (7)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered '3'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 22:35:34

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:34:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered '0'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 22:35:34

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:34:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered '0'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 22:35:34

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Folder: Adverse Events

Form: Adverse Events (7)

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered '0'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 22:35:34

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:34:29

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered 'Not Related (NOT RELATED)'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 22:35:34

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:34:29

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered 'Not Related (NOT RELATED)'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 22:35:34

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:34:29

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered 'Not Applicable (NOT APPLICABLE)'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 22:35:34

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:34:29

None

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered '0'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 22:35:34

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:34:29

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered 'I'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 22:35:34

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:34:29

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 16:23:00
Query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' answered with 'Concomitant Procedure added in log. ' (Site from DM).	Jessie Downs (b) (4) (b) (4)	30 Jan 2021 15:53:33
User opened query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 13:27:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered 'I'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 22:35:34

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:34:29

[Outcome](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 22:35:34

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:34:29

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 22:35:34

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:34:29

[Narrative](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:12
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	22 Oct 2020 12:19:41
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	22 Oct 2020 12:19:41
User entered 'Profound metabolic acidosis secondary to septic shock, sever sepsis, requiring intubation-exubated on the next day 02SEP2020.' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:19:41
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	21 Oct 2020 22:35:34
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 22:35:34

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:34:29

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
User entered 'I'	System	21 Oct 2020 22:35:34

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:34:29

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
User entered 'I'	System	21 Oct 2020 22:35:34

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:34:29

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Nov 2020 01:21:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 17:26:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Nov 2020 02:37:46
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	30 Oct 2020 19:48:29
User entered 'I'	System	21 Oct 2020 22:35:34

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:34:29

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:07:02
User closed query 'Per CDM Review: The participant has indicated that they have received facial cosmetic injections on the Cosmetic Injection_ Dermal Filler eDiary form. However, there are no concomitant medications or medical history terms that correspond to a dermal filler. Please review and clarify or reconcile. ' (Site from DM).	(b) (4), (b) (6)	27 Apr 2021 11:47:30
Query 'Per CDM Review: The participant has indicated that they have received facial cosmetic injections on the Cosmetic Injection_ Dermal Filler eDiary form. However, there are no concomitant medications or medical history terms that correspond to a dermal filler. Please review and clarify or reconcile. ' answered with 'Sub I contacted subject and subject recorded entry in error. Sub I recorded note in telephone contact. ' (Site from DM).	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 17:57:45
User opened query 'Per CDM Review: The participant has indicated that they have received facial cosmetic injections on the Cosmetic Injection_ Dermal Filler eDiary form. However, there are no concomitant medications or medical history terms that correspond to a dermal filler. Please review and clarify or reconcile. ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 17:03:49
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:26:42
User closed query 'Per ETRTR: Please add details for ConMeds dosed for SAEs "Acute Pyelonephritis" and "Septic Shock", thanks.' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 00:32:34
User entered 'Yes (Y)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	27 Oct 2020 18:27:44
Query 'Per ETRTR: Please add details for ConMeds dosed for SAEs "Acute Pyelonephritis" and "Septic Shock", thanks.' answered with 'Unknown at this time. Pending Medical records.' (Site from CRA).	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 18:58:52

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:34:29

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User opened query 'Per ETRTR: Please add details for ConMeds dosed for SAEs "Acute Pyelonephritis" and "Septic Shock", thanks.' (Site from CRA).	(b) (4), (b) (6)	15 Sep 2020 16:33:38
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	02 Sep 2020 20:48:54

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:34:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:40:47
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Dec 2020 14:34:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Dec 2020 14:34:00
Data point term sent to Coder	System	16 Dec 2020 14:33:20
Data point term sent to Coder	System	16 Dec 2020 14:32:19
Coding entries removed.	Jessie Downs (b) (4)	16 Dec 2020 14:32:09
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 17:27:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 17:27:31
Data point term sent to Coder	System	27 Oct 2020 18:29:01
User entered 'Zofran'	Mariete Rendon (b) (4)	27 Oct 2020 18:28:37

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:34:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:40:47
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'No (N)'	Mariete Rendon (b) (4)	27 Oct 2020 18:28:37

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:34:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:40:47
User closed query 'Per DM CLR Requery: Previous response noted. However, there is no Diary event that matches this Con med indication. Review if this should be recorded as an Adverse Event (unsolicited). Else, provide clarification if this will not be recorded on AE ecrf' (Site from DM). User signature succeeded.	(b) (4), (b) (6) Mark Kutner (b) (4) (b) (4)	23 Feb 2021 18:20:36 16 Feb 2021 15:04:52
Query 'Per DM CLR Requery: Previous response noted. However, there is no Diary event that matches this Con med indication. Review if this should be recorded as an Adverse Event (unsolicited). Else, provide clarification if this will not be recorded on AE ecrf' answered with 'Medication was taken due to AE reported.' (Site from DM).	Jessie Downs (b) (4) (b) (4)	30 Jan 2021 15:45:14
User opened query 'Per DM CLR Requery: Previous response noted. However, there is no Diary event that matches this Con med indication. Review if this should be recorded as an Adverse Event (unsolicited). Else, provide clarification if this will not be recorded on AE ecrf' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 14:45:17
Query 'Per DM CLR Requery: Previous response noted. However, there is no Dairy event that matches this Con med indication. Review if this should be recorded as an Adverse Event (unsolicited). Else, provide clarification if this will not be recorded on AE ecrf.' canceled (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 14:44:59
User opened query 'Per DM CLR Requery: Previous response noted. However, there is no Dairy event that matches this Con med indication. Review if this should be recorded as an Adverse Event (unsolicited). Else, provide clarification if this will not be recorded on AE ecrf.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 14:44:43

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:34:29

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	24 Dec 2020 04:17:52
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' answered with 'This was for a SARs not an AE.' (Site from DM).	Jessie Downs (b) (4) (b) (4)	18 Dec 2020 16:27:40
User entered 'VOMiTING' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	16 Dec 2020 14:32:23
DataPoint Un-verified.	Jessie Downs (b) (4) (b) (4)	16 Dec 2020 14:32:09
User entered 'VOMTING' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	16 Dec 2020 14:32:09
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 09:50:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'vomtiing'	Mariete Rendon (b) (4) (b) (4)	27 Oct 2020 18:28:37

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:34:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:40:47
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered '4'	Mariete Rendon (b) (4)	27 Oct 2020 18:28:37
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:34:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:40:47
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'mg (mg)'	Mariete Rendon (b) (4)	27 Oct 2020 18:28:37

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:34:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:40:47
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered empty.	Mariete Rendon (b) (4)	27 Oct 2020 18:28:37
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:34:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:40:47
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'three times daily (TID)'	Mariete Rendon (b) (4)	27 Oct 2020 18:28:37
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:34:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:40:47
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered empty.	Mariete Rendon (b) (4)	27 Oct 2020 18:28:37
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:34:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:40:47
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'Oral (ORAL)'	Mariete Rendon (b) (4)	27 Oct 2020 18:28:37
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:34:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:40:47
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered empty.	Mariete Rendon (b) (4)	27 Oct 2020 18:28:37
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:34:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:40:47
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered '29 Aug 2020'	Mariete Rendon (b) (4)	27 Oct 2020 18:28:37
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:34:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:40:47
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered '0'	Mariete Rendon (b) (4)	27 Oct 2020 18:28:37
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:34:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:40:47
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'No (N)'	Mariete Rendon (b) (4)	27 Oct 2020 18:28:37
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:34:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:40:47
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered '31 Aug 2020'	Mariete Rendon (b) (4)	27 Oct 2020 18:28:37
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:34:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:40:47
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'No (N)'	Mariete Rendon (b) (4)	27 Oct 2020 18:28:37
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:34:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:40:47
User entered '3'	System	27 Oct 2020 18:28:37

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:34:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:40:47
User entered '1'	System	27 Oct 2020 18:28:37

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:34:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:40:47
User entered '804 (804)'	System	27 Oct 2020 18:28:37

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:34:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:44:00
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: OTHER CARDIAC PREPARATIONS, ATC: OTHER CARDIAC PREPARATIONS, PRODUCT: ADENOSINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Oct 2020 20:53:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Oct 2020 20:53:30
Data point term sent to Coder	System	27 Oct 2020 18:31:03
User entered 'adenosine 6mg x2 vials'	Mariete Rendon (b) (4)	27 Oct 2020 18:30:49

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:34:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:44:00
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'No (N)'	Mariete Rendon (b) (4)	27 Oct 2020 18:30:49
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:34:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:44:00
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'tachychardia'	Mariete Rendon (b) (4)	27 Oct 2020 18:30:49
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:34:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:44:00
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered '12'	Mariete Rendon (b) (4)	27 Oct 2020 18:30:49
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:34:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:44:00
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'mg (mg)'	Mariete Rendon (b) (4)	27 Oct 2020 18:30:49
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:34:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:44:00
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered empty.	Mariete Rendon (b) (4)	27 Oct 2020 18:30:49
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:34:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:44:00
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'once (ONCE)'	Mariete Rendon (b) (4)	27 Oct 2020 18:30:49
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:34:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:44:00
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered empty.	Mariete Rendon (b) (4)	27 Oct 2020 18:30:49
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:34:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:44:00
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'Intravenous (INTRAVENOUS)'	Mariete Rendon (b) (4)	27 Oct 2020 18:30:49
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:34:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:44:00
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered empty.	Mariete Rendon (b) (4)	27 Oct 2020 18:30:49
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:34:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:44:00
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered '01 Sep 2020'	Mariete Rendon (b) (4)	27 Oct 2020 18:30:49
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:34:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:44:00
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered '0'	Mariete Rendon (b) (4)	27 Oct 2020 18:30:49
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:34:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:44:00
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'No (N)'	Mariete Rendon (b) (4)	27 Oct 2020 18:30:49
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:34:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:44:00
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered '01 Sep 2020'	Mariete Rendon (b) (4)	27 Oct 2020 18:30:49
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:34:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:44:00
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'No (N)'	Mariete Rendon (b) (4)	27 Oct 2020 18:30:49
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:34:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:44:00
User entered empty.	System	27 Oct 2020 18:30:49

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:34:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:44:00
User entered empty.	System	27 Oct 2020 18:30:49

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:34:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:44:00
User entered empty.	System	27 Oct 2020 18:30:49

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:34:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:44:50
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: ANTIARRHYTHMICS, CLASS I AND III, ATC: ANTIARRHYTHMICS, CLASS III, PRODUCT: AMIODARONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Oct 2020 21:21:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Oct 2020 21:21:30
Data point term sent to Coder	System	27 Oct 2020 18:32:04
User entered 'amiodarone'	Mariete Rendon (b) (4)	27 Oct 2020 18:31:32

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:34:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:44:50
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'No (N)'	Mariete Rendon (b) (4)	27 Oct 2020 18:31:32
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:34:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:44:50
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'tachychardia'	Mariete Rendon (b) (4)	27 Oct 2020 18:31:32
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:34:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:44:50
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered '150'	Mariete Rendon (b) (4)	27 Oct 2020 18:31:32
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:34:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:44:50
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'mg (mg)'	Mariete Rendon (b) (4)	27 Oct 2020 18:31:32

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:34:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:44:50
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered empty.	Mariete Rendon (b) (4)	27 Oct 2020 18:31:32
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:34:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:44:50
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'once (ONCE)'	Mariete Rendon (b) (4)	27 Oct 2020 18:31:32
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:34:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:44:50
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered empty.	Mariete Rendon (b) (4)	27 Oct 2020 18:31:32
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:34:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:44:50
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'Intravenous (INTRAVENOUS)'	Mariete Rendon (b) (4)	27 Oct 2020 18:31:32
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:34:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:44:50
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered empty.	Mariete Rendon (b) (4)	27 Oct 2020 18:31:32
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:34:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:44:50
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered '01 Sep 2020'	Mariete Rendon (b) (4)	27 Oct 2020 18:31:32
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:34:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:44:50
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered '0'	Mariete Rendon (b) (4)	27 Oct 2020 18:31:32
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:34:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:44:50
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'No (N)'	Mariete Rendon (b) (4)	27 Oct 2020 18:31:32
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:34:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:44:50
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered '01 Sep 2020'	Mariete Rendon (b) (4)	27 Oct 2020 18:31:32
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:34:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:44:50
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'No (N)'	Mariete Rendon (b) (4)	27 Oct 2020 18:31:32
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:34:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:44:50
User entered empty.	System	27 Oct 2020 18:31:32

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:34:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:44:50
User entered empty.	System	27 Oct 2020 18:31:32

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:34:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:44:50
User entered empty.	System	27 Oct 2020 18:31:32

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:34:29

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:46:37
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: GLYCOPEPTIDE ANTIBACTERIALS, PRODUCT: VANCOMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 17:26:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 17:26:29
Data point term sent to Coder	System	27 Oct 2020 18:33:05
User entered 'vancomycin'	Mariete Rendon (b) (4)	27 Oct 2020 18:32:57

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:34:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:46:37
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'No (N)'	Mariete Rendon (b) (4)	27 Oct 2020 18:32:57
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:34:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:46:37
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'pnelonephritis/septic shock'	Mariete Rendon (b) (4)	27 Oct 2020 18:32:57
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:34:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:46:37
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered '2'	Mariete Rendon (b) (4)	27 Oct 2020 18:32:57
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:34:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:46:37
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'g (g)'	Mariete Rendon (b) (4)	27 Oct 2020 18:32:57
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:34:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:46:37
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered empty.	Mariete Rendon (b) (4)	27 Oct 2020 18:32:57
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:34:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:46:37
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'once (ONCE)'	Mariete Rendon (b) (4)	27 Oct 2020 18:32:57
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:34:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:46:37
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered empty.	Mariete Rendon (b) (4)	27 Oct 2020 18:32:57
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:34:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:46:37
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'Intravenous (INTRAVENOUS)'	Mariete Rendon (b) (4)	27 Oct 2020 18:32:57
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:34:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:46:37
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered empty.	Mariete Rendon (b) (4)	27 Oct 2020 18:32:57
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:34:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:46:37
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered '01 Sep 2020'	Mariete Rendon (b) (4)	27 Oct 2020 18:32:57
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:34:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:46:37
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered '0'	Mariete Rendon (b) (4)	27 Oct 2020 18:32:57
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:34:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:46:37
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'No (N)'	Mariete Rendon (b) (4)	27 Oct 2020 18:32:57
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:34:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:46:37
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered '01 Sep 2020'	Mariete Rendon (b) (4)	27 Oct 2020 18:32:57
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:34:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:46:37
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'No (N)'	Mariete Rendon (b) (4)	27 Oct 2020 18:32:57
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:34:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:46:37
User entered empty.	System	27 Oct 2020 18:32:57

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:34:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:46:37
User entered empty.	System	27 Oct 2020 18:32:57

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:34:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:46:37
User entered empty.	System	27 Oct 2020 18:32:57

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:34:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:46:46
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FOURTH-GENERATION CEPHALOSPORINS, PRODUCT: CEFEPIME - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Oct 2020 21:40:30
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Oct 2020 21:40:30
	(b) (4)	
Data point term sent to Coder	System	27 Oct 2020 18:35:07
User entered 'cefepime 1 gram each'	Mariete Rendon (b) (4)	27 Oct 2020 18:34:49
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:34:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:46:46
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'No (N)'	Mariete Rendon (b) (4)	27 Oct 2020 18:34:49
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:34:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:46:46
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'pyelonephritis/septic shock'	Mariete Rendon (b) (4)	27 Oct 2020 18:34:49

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:34:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:46:46
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered '2'	Mariete Rendon (b) (4)	27 Oct 2020 18:34:49
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:34:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:46:46
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'g (g)'	Mariete Rendon (b) (4)	27 Oct 2020 18:34:49
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:34:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:46:46
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered empty.	Mariete Rendon (b) (4)	27 Oct 2020 18:34:49
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:34:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:46:46
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'once daily (QD)'	Mariete Rendon (b) (4)	27 Oct 2020 18:34:49
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:34:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:46:46
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered empty.	Mariete Rendon (b) (4)	27 Oct 2020 18:34:49
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:34:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:46:46
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'Intravenous (INTRAVENOUS)'	Mariete Rendon (b) (4)	27 Oct 2020 18:34:49
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:34:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:46:46
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered empty.	Mariete Rendon (b) (4)	27 Oct 2020 18:34:49
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:34:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:46:46
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered '01 Sep 2020'	Mariete Rendon (b) (4)	27 Oct 2020 18:34:49
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:34:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:46:46
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered '0'	Mariete Rendon (b) (4)	27 Oct 2020 18:34:49
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:34:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:46:46
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'No (N)'	Mariete Rendon (b) (4)	27 Oct 2020 18:34:49
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:34:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:46:46
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered '02 Sep 2020'	Mariete Rendon (b) (4)	27 Oct 2020 18:34:49
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:34:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:46:46
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'No (N)'	Mariete Rendon (b) (4)	27 Oct 2020 18:34:49
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:34:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:46:46
User entered '1'	System	27 Oct 2020 18:34:49

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:34:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:46:46
User entered '1'	System	27 Oct 2020 18:34:49

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:34:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:46:46
User entered '804 (804)'	System	27 Oct 2020 18:34:49

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:34:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:46:51
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Oct 2020 21:40:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Oct 2020 21:40:30
Data point term sent to Coder	System	27 Oct 2020 18:37:09
User entered 'ceftriaxone'	Mariete Rendon (b) (4)	27 Oct 2020 18:36:15

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:34:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:46:51
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'No (N)'	Mariete Rendon (b) (4)	27 Oct 2020 18:36:15
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:34:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:46:51
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'pyelonephritis'	Mariete Rendon (b) (4)	27 Oct 2020 18:36:15
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:34:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:46:51
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'I'	Mariete Rendon (b) (4)	27 Oct 2020 18:36:15
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:34:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:46:51
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'g (g)'	Mariete Rendon (b) (4)	27 Oct 2020 18:36:15
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:34:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:46:51
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered empty.	Mariete Rendon (b) (4)	27 Oct 2020 18:36:15
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:34:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:46:51
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:33:16
DataPoint Un-verified.	Mariete Rendon (b) (4)	23 Apr 2021 19:43:32
Signature has been broken.	Mariete Rendon (b) (4)	23 Apr 2021 19:43:32
User entered 'twice daily (BID)' reason for change: Data Entry Error	Mariete Rendon (b) (4)	23 Apr 2021 19:43:32
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 02:23:59
User closed query 'Per source, Q24h' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 02:23:57
Query 'Per source, Q24h' answered with 'Data was updated.' (Site from CRA).	Jessie Downs (b) (4)	12 Nov 2020 19:59:36
User entered 'other (OTHER)' reason for change: Data Entry Error	Jessie Downs (b) (4)	12 Nov 2020 19:59:23
User opened query 'Per source, Q24h' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 18:43:24
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 18:43:09
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'twice daily (BID)'	Mariete Rendon (b) (4)	27 Oct 2020 18:36:15

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:34:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:46:51
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:33:16
	(b) (4)	
DataPoint Un-verified.	Mariete Rendon (b) (4)	23 Apr 2021 19:43:32
	(b) (4)	
Signature has been broken.	Mariete Rendon (b) (4)	23 Apr 2021 19:43:32
	(b) (4)	
User entered empty; reason for change Data Entry Error	Mariete Rendon (b) (4)	23 Apr 2021 19:43:32
	(b) (4)	
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 02:24:00
DataPoint Un-verified.	Jessie Downs (b) (4)	12 Nov 2020 19:59:23
	(b) (4)	
User entered 'every 24 hours' reason for change: Data Entry Error	Jessie Downs (b) (4)	12 Nov 2020 19:59:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered empty.	Mariete Rendon (b) (4)	27 Oct 2020 18:36:15
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:34:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:46:51
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'Intravenous (INTRAVENOUS)'	Mariete Rendon (b) (4)	27 Oct 2020 18:36:15
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:34:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:46:51
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered empty.	Mariete Rendon (b) (4)	27 Oct 2020 18:36:15
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:34:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:46:51
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered '03 Sep 2020'	Mariete Rendon (b) (4)	27 Oct 2020 18:36:15
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:34:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:46:51
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered '0'	Mariete Rendon (b) (4)	27 Oct 2020 18:36:15
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:34:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:46:51
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'No (N)'	Mariete Rendon (b) (4)	27 Oct 2020 18:36:15
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:34:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:46:51
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered '04 Sep 2020'	Mariete Rendon (b) (4)	27 Oct 2020 18:36:15
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:34:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:46:51
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'No (N)'	Mariete Rendon (b) (4)	27 Oct 2020 18:36:15
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:34:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:46:51
User entered '2'	System	23 Apr 2021 19:43:32
User entered empty.	System	12 Nov 2020 19:59:23
User entered '2'	System	27 Oct 2020 18:36:15

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:34:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:46:51
User entered '1'	System	23 Apr 2021 19:43:32
User entered empty.	System	12 Nov 2020 19:59:23
User entered '1'	System	27 Oct 2020 18:36:15

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:34:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:46:51
User entered '804 (804)'	System	23 Apr 2021 19:43:32
User entered empty.	System	12 Nov 2020 19:59:23
User entered '804 (804)'	System	27 Oct 2020 18:36:15

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:34:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:46:56
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: SULFONAMIDES AND TRIMETHOPRIM, ATC: COMBINATIONS OF SULFONAMIDES AND TRIMETHOPRIM, INCL. DERIVATIVES, PRODUCT: SULFAMETHOXAZOLE;TRIMETHOPRIM, PRODUCTSYNONYM: BACTRIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Oct 2020 21:25:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Oct 2020 21:25:35
Data point term sent to Coder	System	27 Oct 2020 18:38:11
User entered 'bactrin (trinethoprim/sulfamethoxazole)'	Mariete Rendon (b) (4)	27 Oct 2020 18:37:57

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:34:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:46:56
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'No (N)'	Mariete Rendon (b) (4)	27 Oct 2020 18:37:57
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:34:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:46:56
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'pyelonephritis'	Mariete Rendon (b) (4)	27 Oct 2020 18:37:57
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:34:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:46:56
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:33:16
DataPoint Un-verified.	Mariete Rendon (b) (4)	23 Apr 2021 19:45:04
Signature has been broken.	Mariete Rendon (b) (4)	23 Apr 2021 19:45:04
User entered '800/160' reason for change: Data Entry Error	Mariete Rendon (b) (4)	23 Apr 2021 19:45:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 02:24:15
User closed query 'This should be 160/800 (160 of trimethoprim/ 800 of sulfamethoxazole). Please correct here and on source/conmed log.' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 02:24:13
Query 'This should be 160/800 (160 of trimethoprim/ 800 of sulfamethoxazole). Please correct here and on source/conmed log.' answered with 'Data was updated.' (Site from CRA).	Jessie Downs (b) (4)	12 Nov 2020 20:57:08
User entered '160/800' reason for change: Data Entry Error	Jessie Downs (b) (4)	12 Nov 2020 20:56:58
User opened query 'This should be 160/800 (160 of trimethoprim/ 800 of sulfamethoxazole). Please correct here and on source/conmed log.' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 18:58:03
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 18:56:44
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered '800/160'	Mariete Rendon (b) (4)	27 Oct 2020 18:37:57

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:34:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:46:56
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'mg (mg)'	Mariete Rendon (b) (4)	27 Oct 2020 18:37:57
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:34:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:46:56
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered empty.	Mariete Rendon (b) (4)	27 Oct 2020 18:37:57
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:34:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:46:56
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'twice daily (BID)'	Mariete Rendon (b) (4)	27 Oct 2020 18:37:57
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:34:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:46:56
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered empty.	Mariete Rendon (b) (4)	27 Oct 2020 18:37:57
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:34:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:46:56
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'Oral (ORAL)'	Mariete Rendon (b) (4)	27 Oct 2020 18:37:57
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:34:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:46:56
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered empty.	Mariete Rendon (b) (4)	27 Oct 2020 18:37:57
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:34:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:46:56
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered '04 Sep 2020'	Mariete Rendon (b) (4)	27 Oct 2020 18:37:57
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:34:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:46:56
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered '0'	Mariete Rendon (b) (4)	27 Oct 2020 18:37:57
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:34:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:46:56
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'No (N)'	Mariete Rendon (b) (4)	27 Oct 2020 18:37:57
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:34:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:46:56
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
User closed query 'End Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	04 Dec 2020 21:08:41
User opened query 'End Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	04 Dec 2020 20:55:19
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered '18 Sep 2020'	Mariete Rendon (b) (4)	27 Oct 2020 18:37:57

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:34:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:46:56
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'No (N)'	Mariete Rendon (b) (4)	27 Oct 2020 18:37:57
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:34:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:46:56
User entered '2'	System	27 Oct 2020 18:37:57

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:34:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:46:56
User entered '1'	System	27 Oct 2020 18:37:57

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:34:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:46:56
User entered '804 (804)'	System	27 Oct 2020 18:37:57

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:34:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:48:03
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
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)	27 Oct 2020 18:40:30
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Oct 2020 18:40:30
	(b) (4)	
Data point term sent to Coder	System	27 Oct 2020 18:39:12
User entered 'tylenol'	Mariete Rendon (b) (4)	27 Oct 2020 18:38:44
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:34:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:48:03
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'No (N)'	Mariete Rendon (b) (4)	27 Oct 2020 18:38:44
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:34:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:48:03
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.'	(b) (4), (b) (6)	24 Dec 2020 04:17:21
(Site from DM).		
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.'	Jessie Downs (b) (4)	18 Dec 2020 16:30:15
' answered with 'This was for a SARs not an AE.'	(b) (4)	
(Site from DM).		
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.'	(b) (4), (b) (6)	16 Dec 2020 09:49:07
(Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'fever'	Mariete Rendon (b) (4)	27 Oct 2020 18:38:44
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:34:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:48:03
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered '325'	Mariete Rendon (b) (4)	27 Oct 2020 18:38:44
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:34:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:48:03
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'mg (mg)'	Mariete Rendon (b) (4)	27 Oct 2020 18:38:44
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:34:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:48:03
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered empty.	Mariete Rendon (b) (4)	27 Oct 2020 18:38:44
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:34:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:48:03
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'once (ONCE)'	Mariete Rendon (b) (4)	27 Oct 2020 18:38:44
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:34:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:48:03
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered empty.	Mariete Rendon (b) (4)	27 Oct 2020 18:38:44
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:34:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:48:03
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'Rectal (RECTAL)'	Mariete Rendon (b) (4)	27 Oct 2020 18:38:44
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:34:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:48:03
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered empty.	Mariete Rendon (b) (4)	27 Oct 2020 18:38:44
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:34:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:48:03
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered '01 Sep 2020'	Mariete Rendon (b) (4)	27 Oct 2020 18:38:44
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:34:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:48:03
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered '0'	Mariete Rendon (b) (4)	27 Oct 2020 18:38:44
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:34:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:48:03
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'No (N)'	Mariete Rendon (b) (4)	27 Oct 2020 18:38:44
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:34:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:48:03
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered '01 Sep 2020'	Mariete Rendon (b) (4)	27 Oct 2020 18:38:44
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:34:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:48:03
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'No (N)'	Mariete Rendon (b) (4)	27 Oct 2020 18:38:44
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:34:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:48:03
User entered empty.	System	27 Oct 2020 18:38:44

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:34:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:48:03
User entered empty.	System	27 Oct 2020 18:38:44

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:34:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:48:03
User entered empty.	System	27 Oct 2020 18:38:44

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:34:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:48:06
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Oct 2020 22:15:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Oct 2020 22:15:38
Data point term sent to Coder	System	27 Oct 2020 18:41:16
User entered 'famotidine'	Mariete Rendon (b) (4)	27 Oct 2020 18:40:45

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:34:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:48:06
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'No (N)'	Mariete Rendon (b) (4)	27 Oct 2020 18:40:45
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:34:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:48:06
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	24 Dec 2020 04:17:27
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'This was for a SARs not an AE.' (Site from DM).	Jessie Downs (b) (4)	18 Dec 2020 16:30:48
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 09:48:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'vomiting/nausea'	Mariete Rendon (b) (4)	27 Oct 2020 18:40:45

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:34:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:48:06
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'I'	Mariete Rendon (b) (4)	27 Oct 2020 18:40:45
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:34:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:48:06
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'Other (OTHER)'	Mariete Rendon (b) (4)	27 Oct 2020 18:40:45
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:34:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:48:06
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'vial 20mg/2ml'	Mariete Rendon (b) (4)	27 Oct 2020 18:40:45
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:34:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:48:06
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'once daily (QD)'	Mariete Rendon (b) (4)	27 Oct 2020 18:40:45
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:34:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:48:06
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered empty.	Mariete Rendon (b) (4)	27 Oct 2020 18:40:45
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:34:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:48:06
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'Intravenous (INTRAVENOUS)'	Mariete Rendon (b) (4)	27 Oct 2020 18:40:45
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:34:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:48:06
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered empty.	Mariete Rendon (b) (4)	27 Oct 2020 18:40:45
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:34:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:48:06
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered '01 Sep 2020'	Mariete Rendon (b) (4)	27 Oct 2020 18:40:45
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:34:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:48:06
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered '0'	Mariete Rendon (b) (4)	27 Oct 2020 18:40:45
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:34:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:48:06
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'No (N)'	Mariete Rendon (b) (4)	27 Oct 2020 18:40:45
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:34:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:48:06
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered '03 Sep 2020'	Mariete Rendon (b) (4)	27 Oct 2020 18:40:45
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:34:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:48:06
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'No (N)'	Mariete Rendon (b) (4)	27 Oct 2020 18:40:45
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:34:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:48:06
User entered '1'	System	27 Oct 2020 18:40:45

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:34:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:48:06
User entered '1'	System	27 Oct 2020 18:40:45

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:34:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:48:06
User entered '804 (804)'	System	27 Oct 2020 18:40:45

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:34:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:48:52
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OPIOID ANESTHETICS, PRODUCT: FENTANYL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Oct 2020 22:16:26
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Oct 2020 22:16:26
	(b) (4)	
Data point term sent to Coder	System	27 Oct 2020 18:42:18
User entered 'fentanyl'	Mariete Rendon (b) (4)	27 Oct 2020 18:42:10
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:34:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:48:52
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'No (N)'	Mariete Rendon (b) (4)	27 Oct 2020 18:42:10
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:34:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:48:52
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'right upper quadrant pain abdomen'	Mariete Rendon (b) (4)	27 Oct 2020 18:42:10

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:34:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:48:52
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'I'	Mariete Rendon (b) (4)	27 Oct 2020 18:42:10
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:34:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:48:52
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'Other (OTHER)'	Mariete Rendon (b) (4)	27 Oct 2020 18:42:10
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:34:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:48:52
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'vial 25mcg/0.5ml'	Mariete Rendon (b) (4)	27 Oct 2020 18:42:10
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:34:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:48:52
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'other (OTHER)'	Mariete Rendon (b) (4)	27 Oct 2020 18:42:10
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:34:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:48:52
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'every 2 hours/ as needed'	Mariete Rendon (b) (4)	27 Oct 2020 18:42:10
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:34:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:48:52
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'Intravenous (INTRAVENOUS)'	Mariete Rendon (b) (4)	27 Oct 2020 18:42:10
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:34:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:48:52
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered empty.	Mariete Rendon (b) (4)	27 Oct 2020 18:42:10
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:34:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:48:52
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered '01 Sep 2020'	Mariete Rendon (b) (4)	27 Oct 2020 18:42:10
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:34:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:48:52
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered '0'	Mariete Rendon (b) (4)	27 Oct 2020 18:42:10
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:34:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:48:52
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'No (N)'	Mariete Rendon (b) (4)	27 Oct 2020 18:42:10
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:34:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:48:52
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered '02 Sep 2020'	Mariete Rendon (b) (4)	27 Oct 2020 18:42:10
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:34:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:48:52
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'No (N)'	Mariete Rendon (b) (4)	27 Oct 2020 18:42:10
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:34:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:48:52
User entered empty.	System	27 Oct 2020 18:42:10

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:34:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:48:52
User entered empty.	System	27 Oct 2020 18:42:10

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:34:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:48:52
User entered empty.	System	27 Oct 2020 18:42:10

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:34:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:06
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: CALCIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM LACTATE, PRODUCTSYNONYM: LACTATED RINGER - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	27 Oct 2020 18:45:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	(b) (4)	27 Oct 2020 18:45:34
Data point term sent to Coder	System	27 Oct 2020 18:44:21
User entered 'lactated ringer'	Mariete Rendon (b) (4)	27 Oct 2020 18:44:06

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:34:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:06
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'No (N)'	Mariete Rendon (b) (4)	27 Oct 2020 18:44:06
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:34:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:06
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'metabolic acidosis'	Mariete Rendon (b) (4)	27 Oct 2020 18:44:06
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:34:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:06
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered '1000'	Mariete Rendon (b) (4)	27 Oct 2020 18:44:06
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:34:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:06
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'mL (mL)'	Mariete Rendon (b) (4)	27 Oct 2020 18:44:06
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:34:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:06
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered empty.	Mariete Rendon (b) (4)	27 Oct 2020 18:44:06
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:34:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:06
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'once (ONCE)'	Mariete Rendon (b) (4)	27 Oct 2020 18:44:06
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:34:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:06
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered empty.	Mariete Rendon (b) (4)	27 Oct 2020 18:44:06
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:34:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:06
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'Intravenous (INTRAVENOUS)'	Mariete Rendon (b) (4)	27 Oct 2020 18:44:06
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:34:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:06
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered empty.	Mariete Rendon (b) (4)	27 Oct 2020 18:44:06
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:34:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:06
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered '01 Sep 2020'	Mariete Rendon (b) (4)	27 Oct 2020 18:44:06
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:34:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:06
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered '0'	Mariete Rendon (b) (4)	27 Oct 2020 18:44:06
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:34:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:06
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'No (N)'	Mariete Rendon (b) (4)	27 Oct 2020 18:44:06
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:34:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:06
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered '01 Sep 2020'	Mariete Rendon (b) (4)	27 Oct 2020 18:44:06
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:34:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:06
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'No (N)'	Mariete Rendon (b) (4)	27 Oct 2020 18:44:06
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:34:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:06
User entered empty.	System	27 Oct 2020 18:44:06

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:34:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:06
User entered empty.	System	27 Oct 2020 18:44:06

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:34:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:06
User entered empty.	System	27 Oct 2020 18:44:06

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:34:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:09
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: CARDIAC STIMULANTS EXCL. CARDIAC GLYCOSIDES, ATC: ADRENERGIC AND DOPAMINERGIC AGENTS, PRODUCT: NOREPINEPHRINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 17:15:42
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 17:15:42
	(b) (4)	
Data point term sent to Coder	System	27 Oct 2020 18:46:25
User entered 'norepinephrine'	Mariete Rendon (b) (4)	27 Oct 2020 18:45:50
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:34:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:09
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'No (N)'	Mariete Rendon (b) (4)	27 Oct 2020 18:45:50
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:34:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:09
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'anesthesia for respiratory tube placement'	Mariete Rendon (b) (4)	27 Oct 2020 18:45:50

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:34:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:09
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered '4'	Mariete Rendon (b) (4)	27 Oct 2020 18:45:50
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:34:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:09
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'mg (mg)'	Mariete Rendon (b) (4)	27 Oct 2020 18:45:50
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:34:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:09
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered empty.	Mariete Rendon (b) (4)	27 Oct 2020 18:45:50
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:34:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:09
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'once (ONCE)'	Mariete Rendon (b) (4)	27 Oct 2020 18:45:50
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:34:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:09
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered empty.	Mariete Rendon (b) (4)	27 Oct 2020 18:45:50
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:34:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:09
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'Intravenous (INTRAVENOUS)'	Mariete Rendon (b) (4)	27 Oct 2020 18:45:50
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:34:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:09
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered empty.	Mariete Rendon (b) (4)	27 Oct 2020 18:45:50
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:34:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:09
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered '01 Sep 2020'	Mariete Rendon (b) (4)	27 Oct 2020 18:45:50
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:34:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:09
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered '0'	Mariete Rendon (b) (4)	27 Oct 2020 18:45:50
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:34:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:09
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'No (N)'	Mariete Rendon (b) (4)	27 Oct 2020 18:45:50
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:34:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:09
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered '01 Sep 2020'	Mariete Rendon (b) (4)	27 Oct 2020 18:45:50
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:34:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:09
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'No (N)'	Mariete Rendon (b) (4)	27 Oct 2020 18:45:50
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:34:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:09
User entered empty.	System	27 Oct 2020 18:45:50

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:34:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:09
User entered empty.	System	27 Oct 2020 18:45:50

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:34:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:09
User entered empty.	System	27 Oct 2020 18:45:50

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:34:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OTHER GENERAL ANESTHETICS, PRODUCT: PROPOFOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 17:19:14
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 17:19:14
Data point term sent to Coder	System	27 Oct 2020 18:46:29
User entered 'propofol'	Mariete Rendon (b) (4)	27 Oct 2020 18:46:27

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:34:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'No (N)'	Mariete Rendon (b) (4)	27 Oct 2020 18:46:27
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:34:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'anesthesia for respiratory tube placement'	Mariete Rendon (b) (4)	27 Oct 2020 18:46:27
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:34:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered '1000'	Mariete Rendon (b) (4)	27 Oct 2020 18:46:27
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:34:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'mg (mg)'	Mariete Rendon (b) (4)	27 Oct 2020 18:46:27
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:34:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered empty.	Mariete Rendon (b) (4)	27 Oct 2020 18:46:27
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:34:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'once (ONCE)'	Mariete Rendon (b) (4)	27 Oct 2020 18:46:27
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:34:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered empty.	Mariete Rendon (b) (4)	27 Oct 2020 18:46:27
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:34:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'Intravenous (INTRAVENOUS)'	Mariete Rendon (b) (4)	27 Oct 2020 18:46:27
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:34:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered empty.	Mariete Rendon (b) (4)	27 Oct 2020 18:46:27
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:34:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered '01 Sep 2020'	Mariete Rendon (b) (4)	27 Oct 2020 18:46:27
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:34:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered '0'	Mariete Rendon (b) (4)	27 Oct 2020 18:46:27
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:34:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'No (N)'	Mariete Rendon (b) (4)	27 Oct 2020 18:46:27
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:34:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered '01 Sep 2020'	Mariete Rendon (b) (4)	27 Oct 2020 18:46:27
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:34:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:04
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'No (N)'	Mariete Rendon (b) (4)	27 Oct 2020 18:46:27
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:34:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:04
User entered empty.	System	27 Oct 2020 18:46:27

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:34:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:04
User entered empty.	System	27 Oct 2020 18:46:27

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:34:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:04
User entered empty.	System	27 Oct 2020 18:46:27

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:34:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:08
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES, ATC: POSTERIOR PITUITARY LOBE HORMONES, ATC: VASOPRESSIN AND ANALOGUES, PRODUCT: VASOPRESSIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 17:26:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 17:26:30
Data point term sent to Coder	System	27 Oct 2020 18:48:36
User entered 'vasopressin'	Mariete Rendon (b) (4)	27 Oct 2020 18:47:40

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:34:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:08
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'No (N)'	Mariete Rendon (b) (4)	27 Oct 2020 18:47:40
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:34:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:08
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.'	(b) (4), (b) (6)	24 Dec 2020 04:17:38
(Site from DM).		
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.'	Jessie Downs (b) (4)	18 Dec 2020 16:31:18
' answered with 'This was for a SARs not an AE.'	(b) (4)	
(Site from DM).		
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.'	(b) (4), (b) (6)	16 Dec 2020 09:49:39
(Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'tachycardia/hypotension'	Mariete Rendon (b) (4)	27 Oct 2020 18:47:40
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:34:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:08
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered '50'	Mariete Rendon (b) (4)	27 Oct 2020 18:47:40
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:34:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:08
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'IU (IU)'	Mariete Rendon (b) (4)	27 Oct 2020 18:47:40
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:34:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:08
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered empty.	Mariete Rendon (b) (4)	27 Oct 2020 18:47:40
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:34:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:08
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'once (ONCE)'	Mariete Rendon (b) (4)	27 Oct 2020 18:47:40
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:34:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:08
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered empty.	Mariete Rendon (b) (4)	27 Oct 2020 18:47:40
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:34:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:08
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'Intravenous (INTRAVENOUS)'	Mariete Rendon (b) (4)	27 Oct 2020 18:47:40
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:34:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:08
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered empty.	Mariete Rendon (b) (4)	27 Oct 2020 18:47:40
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:34:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:08
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered '01 Sep 2020'	Mariete Rendon (b) (4)	27 Oct 2020 18:47:40
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:34:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:08
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered '0'	Mariete Rendon (b) (4)	27 Oct 2020 18:47:40
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:34:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:08
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'No (N)'	Mariete Rendon (b) (4)	27 Oct 2020 18:47:40
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:34:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:08
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered '01 Sep 2020'	Mariete Rendon (b) (4)	27 Oct 2020 18:47:40
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:34:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:08
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'No (N)'	Mariete Rendon (b) (4)	27 Oct 2020 18:47:40
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:34:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:08
User entered empty.	System	27 Oct 2020 18:47:40

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:34:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:08
User entered empty.	System	27 Oct 2020 18:47:40

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:34:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:08
User entered empty.	System	27 Oct 2020 18:47:40

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:34:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:18:50
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: POTASSIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 09:11:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 09:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: POTASSIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 17:18:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 17:18:17
Data point term sent to Coder	System	27 Oct 2020 18:49:40
User entered 'potassium chloride'	Mariete Rendon (b) (4) (b) (4)	27 Oct 2020 18:49:37

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:34:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:18:50
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'No (N)'	Mariete Rendon (b) (4)	27 Oct 2020 18:49:37
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:34:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:18:50
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'metabolic acidosis'	Mariete Rendon (b) (4)	27 Oct 2020 18:49:37
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:34:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:18:50
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'I'	Mariete Rendon (b) (4)	27 Oct 2020 18:49:37
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:34:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:18:50
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'Other (OTHER)'	Mariete Rendon (b) (4)	27 Oct 2020 18:49:37
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:34:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:18:50
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 02:24:42
User closed query 'Per source, 40 mEq/100 mL.' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 02:24:39
Query 'Per source, 40 mEq/100 mL.' answered with 'Data was updated.' (Site from CRA).	Jessie Downs (b) (4)	12 Nov 2020 20:58:00
User entered '40 mEq/100 mL' reason for change: Data Entry Error	(b) (4)	12 Nov 2020 20:57:43
User opened query 'Per source, 40 mEq/100 mL.' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 18:48:46
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 18:48:15
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'vial 40mcg/100ml'	Mariete Rendon (b) (4)	27 Oct 2020 18:49:37
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:34:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:18:50
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'once (ONCE)'	Mariete Rendon (b) (4)	27 Oct 2020 18:49:37
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:34:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:18:50
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered empty.	Mariete Rendon (b) (4)	27 Oct 2020 18:49:37
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:34:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:18:50
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'Intravenous (INTRAVENOUS)'	Mariete Rendon (b) (4)	27 Oct 2020 18:49:37

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:34:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:18:50
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered empty.	Mariete Rendon (b) (4)	27 Oct 2020 18:49:37
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:34:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:18:50
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered '01 Sep 2020'	Mariete Rendon (b) (4)	27 Oct 2020 18:49:37
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:34:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:18:50
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered '0'	Mariete Rendon (b) (4)	27 Oct 2020 18:49:37
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:34:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:18:50
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'No (N)'	Mariete Rendon (b) (4)	27 Oct 2020 18:49:37
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:34:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:18:50
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered '01 Sep 2020'	Mariete Rendon (b) (4)	27 Oct 2020 18:49:37
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:34:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:18:50
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'No (N)'	Mariete Rendon (b) (4)	27 Oct 2020 18:49:37
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:34:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:18:50
User entered empty.	System	27 Oct 2020 18:49:37

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:34:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:18:50
User entered empty.	System	27 Oct 2020 18:49:37

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:34:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:18:50
User entered empty.	System	27 Oct 2020 18:49:37

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:34:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:20:27
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM BICARBONATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Apr 2021 10:10:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	19 Apr 2021 10:10:41
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM BICARBONATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 17:24:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	29 Oct 2020 17:24:56
Data point term sent to Coder	System	27 Oct 2020 19:00:00
User entered 'sodium bicarbonate 8.4%'	Mariete Rendon (b) (4)	27 Oct 2020 18:59:49

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:34:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:20:27
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'No (N)'	Mariete Rendon (b) (4)	27 Oct 2020 18:59:49
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:34:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:20:27
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'metabolic acidosis'	Mariete Rendon (b) (4)	27 Oct 2020 18:59:49
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:34:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:20:27
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered '100/50'	Mariete Rendon (b) (4)	27 Oct 2020 18:59:49
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:34:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:20:27
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
User closed query 'Dose should be mEq/mL' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 02:25:03
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 02:25:01
Query 'Dose should be mEq/mL' answered with 'Data was updated.' (Site from CRA).	Jessie Downs (b) (4)	12 Nov 2020 20:58:58
	(b) (4)	
User entered 'Other (OTHER)' reason for change: Data Entry Error	Jessie Downs (b) (4)	12 Nov 2020 20:58:42
	(b) (4)	
User opened query 'Dose should be mEq/mL' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 18:50:12
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 18:49:49
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'mL (mL)'	Mariete Rendon (b) (4)	27 Oct 2020 18:59:49
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:34:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:20:27
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 02:25:05
DataPoint Un-verified.	Jessie Downs (b) (4)	12 Nov 2020 20:58:42
	(b) (4)	
User entered 'mEq/mL' reason for change: Data Entry Error	Jessie Downs (b) (4)	12 Nov 2020 20:58:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered empty.	Mariete Rendon (b) (4)	27 Oct 2020 18:59:49
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:34:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:20:27
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'once (ONCE)'	Mariete Rendon (b) (4)	27 Oct 2020 18:59:49
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:34:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:20:27
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered empty.	Mariete Rendon (b) (4)	27 Oct 2020 18:59:49
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:34:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:20:27
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'Intravenous (INTRAVENOUS)'	Mariete Rendon (b) (4)	27 Oct 2020 18:59:49
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:34:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:20:27
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered empty.	Mariete Rendon (b) (4)	27 Oct 2020 18:59:49
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:34:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:20:27
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered '01 Sep 2020'	Mariete Rendon (b) (4)	27 Oct 2020 18:59:49
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:34:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:20:27
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered '0'	Mariete Rendon (b) (4)	27 Oct 2020 18:59:49
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:34:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:20:27
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'No (N)'	Mariete Rendon (b) (4)	27 Oct 2020 18:59:49
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:34:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:20:27
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered '01 Sep 2020'	Mariete Rendon (b) (4)	27 Oct 2020 18:59:49
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:34:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:20:27
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'No (N)'	Mariete Rendon (b) (4)	27 Oct 2020 18:59:49
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:34:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:20:27
User entered empty.	System	27 Oct 2020 18:59:49

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:34:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:20:27
User entered empty.	System	27 Oct 2020 18:59:49

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:34:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:20:27
User entered empty.	System	27 Oct 2020 18:59:49

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:34:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:28
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: SODIUM CHLORIDE 0.9% - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Apr 2021 16:16:03
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	18 Apr 2021 16:16:03
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: SODIUM CHLORIDE 0.9% - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 17:24:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	29 Oct 2020 17:24:58
Data point term sent to Coder	System	27 Oct 2020 19:03:06
User entered 'sodium chloride 0.9%'	Mariete Rendon (b) (4)	27 Oct 2020 19:02:54

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:34:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:28
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'No (N)'	Mariete Rendon (b) (4)	27 Oct 2020 19:02:54
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:34:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:28
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'hydration (open line for medication administration)'	Mariete Rendon (b) (4)	27 Oct 2020 19:02:54

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:34:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:28
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered '1000'	Mariete Rendon (b) (4)	27 Oct 2020 19:02:54
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:34:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:28
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'mL (mL)'	Mariete Rendon (b) (4)	27 Oct 2020 19:02:54
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:34:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:28
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered empty.	Mariete Rendon (b) (4)	27 Oct 2020 19:02:54
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:34:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:28
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'once daily (QD)'	Mariete Rendon (b) (4)	27 Oct 2020 19:02:54
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:34:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:28
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered empty.	Mariete Rendon (b) (4)	27 Oct 2020 19:02:54
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:34:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:28
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'Intravenous (INTRAVENOUS)'	Mariete Rendon (b) (4)	27 Oct 2020 19:02:54
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:34:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:28
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered empty.	Mariete Rendon (b) (4)	27 Oct 2020 19:02:54
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:34:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:28
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered '01 Sep 2020'	Mariete Rendon (b) (4)	27 Oct 2020 19:02:54
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:34:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:28
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered '0'	Mariete Rendon (b) (4)	27 Oct 2020 19:02:54
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:34:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:28
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'No (N)'	Mariete Rendon (b) (4)	27 Oct 2020 19:02:54
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:34:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:28
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered '02 Sep 2020'	Mariete Rendon (b) (4)	27 Oct 2020 19:02:54
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:34:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:28
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'No (N)'	Mariete Rendon (b) (4)	27 Oct 2020 19:02:54
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:34:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:28
User entered '1'	System	27 Oct 2020 19:02:54

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:34:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:28
User entered '1'	System	27 Oct 2020 19:02:54

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:34:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:28
User entered '804 (804)'	System	27 Oct 2020 19:02:54

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:34:29

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:28
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: KETOROLAC TROMETHAMINE, PRODUCTSYNONYM: TORADOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 17:25:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	29 Oct 2020 17:25:33
Data point term sent to Coder	System	27 Oct 2020 19:05:08
User entered 'toradol'	Mariete Rendon (b) (4)	27 Oct 2020 19:04:27
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:34:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:28
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'No (N)'	Mariete Rendon (b) (4)	27 Oct 2020 19:04:27
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:34:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:28
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'right upper quadrant abdomen pain'	Mariete Rendon (b) (4)	27 Oct 2020 19:04:27

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:34:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:28
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered '30'	Mariete Rendon (b) (4)	27 Oct 2020 19:04:27
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:34:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:28
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'mg (mg)'	Mariete Rendon (b) (4)	27 Oct 2020 19:04:27

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:34:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:28
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered empty.	Mariete Rendon (b) (4)	27 Oct 2020 19:04:27
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:34:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:28
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'once (ONCE)'	Mariete Rendon (b) (4)	27 Oct 2020 19:04:27
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:34:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:28
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered empty.	Mariete Rendon (b) (4)	27 Oct 2020 19:04:27
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:34:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:28
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'Intravenous (INTRAVENOUS)'	Mariete Rendon (b) (4)	27 Oct 2020 19:04:27
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:34:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:28
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered empty.	Mariete Rendon (b) (4)	27 Oct 2020 19:04:27
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:34:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:28
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered '01 Sep 2020'	Mariete Rendon (b) (4)	27 Oct 2020 19:04:27
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:34:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:28
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered '0'	Mariete Rendon (b) (4)	27 Oct 2020 19:04:27
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:34:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:28
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'No (N)'	Mariete Rendon (b) (4)	27 Oct 2020 19:04:27
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:34:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:28
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered '01 Sep 2020'	Mariete Rendon (b) (4)	27 Oct 2020 19:04:27
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:34:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:28
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'No (N)'	Mariete Rendon (b) (4)	27 Oct 2020 19:04:27
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:34:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:28
User entered empty.	System	27 Oct 2020 19:04:27

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:34:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:28
User entered empty.	System	27 Oct 2020 19:04:27

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:34:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:28
User entered empty.	System	27 Oct 2020 19:04:27

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:34:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:35
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
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)	27 Oct 2020 19:07:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Oct 2020 19:07:29
Data point term sent to Coder	System	27 Oct 2020 19:06:11
User entered 'tylenol'	Mariete Rendon (b) (4)	27 Oct 2020 19:05:34

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:34:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:35
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'No (N)'	Mariete Rendon (b) (4)	27 Oct 2020 19:05:34
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:34:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:35
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'fever'	Mariete Rendon (b) (4)	27 Oct 2020 19:05:34
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:34:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:35
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered '650'	Mariete Rendon (b) (4)	27 Oct 2020 19:05:34
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:34:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:35
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'mg (mg)'	Mariete Rendon (b) (4)	27 Oct 2020 19:05:34

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:34:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:35
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered empty.	Mariete Rendon (b) (4)	27 Oct 2020 19:05:34
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:34:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:35
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'other (OTHER)'	Mariete Rendon (b) (4)	27 Oct 2020 19:05:34
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:34:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:35
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'every 6 hours/ as needed'	Mariete Rendon (b) (4)	27 Oct 2020 19:05:34
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:34:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:35
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'Oral (ORAL)'	Mariete Rendon (b) (4)	27 Oct 2020 19:05:34
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:34:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:35
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered empty.	Mariete Rendon (b) (4)	27 Oct 2020 19:05:34
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:34:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:35
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered '01 Sep 2020'	Mariete Rendon (b) (4)	27 Oct 2020 19:05:34
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:34:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:35
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered '0'	Mariete Rendon (b) (4)	27 Oct 2020 19:05:34
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:34:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:35
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'No (N)'	Mariete Rendon (b) (4)	27 Oct 2020 19:05:34
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:34:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:35
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered '01 Sep 2020'	Mariete Rendon (b) (4)	27 Oct 2020 19:05:34
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:34:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:35
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:33:13
User entered 'No (N)'	Mariete Rendon (b) (4)	27 Oct 2020 19:05:34
	(b) (4)	

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:34:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:35
User entered empty.	System	27 Oct 2020 19:05:34

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:34:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:35
User entered empty.	System	27 Oct 2020 19:05:34

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:34:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:35
User entered empty.	System	27 Oct 2020 19:05:34

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:34:29

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: LEVOFLOXACIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 May 2021 15:46:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 May 2021 15:46:00
Data point term sent to Coder Coding entries removed.	System Jessie Downs (b) (4) (b) (4)	30 Apr 2021 19:42:19 30 Apr 2021 19:41:54
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:56:30
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: LEVOFLOXACIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 14:31:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 14:31:51
Data point term sent to Coder User entered 'Levofloxacin'	System (b) (4), (b) (6)	12 Apr 2021 18:24:15 12 Apr 2021 18:23:17

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:34:29

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:56:30
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4)	12 Apr 2021 18:23:17

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:34:29

[Indication](#)

Audit	User	Time (GMT)
Signature has been broken.	Jessie Downs (b) (4)	30 Apr 2021 19:41:54
	(b) (4)	
User entered 'PROPHYLAXIS AFTER REMOVED STEM RIGHT URETER' reason for change: Data Entry Error	Jessie Downs (b) (4)	30 Apr 2021 19:41:54
	(b) (4)	
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 15:56:30
	(b) (4)	
User entered 'Prophylaxis'	(b) (4), (b) (6)	12 Apr 2021 18:23:17

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:34:29

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:56:30
User entered '500'	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 18:23:17

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:34:29

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:56:30
User entered 'mg (mg)'	(b) (4), (b) (6) (b) (4)	12 Apr 2021 18:23:17

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:34:29

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:56:30
User entered empty.	(b) (4), (b) (6) (b) (4)	12 Apr 2021 18:23:17

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:34:29

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:56:30
User entered 'once daily (QD)'	(b) (4), (b) (6)	12 Apr 2021 18:23:17

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:34:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:56:30
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 18:23:17

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:34:29

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:56:30
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	12 Apr 2021 18:23:17

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:34:29

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:56:30
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 18:23:17

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:34:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:56:30
User entered '06 Apr 2021'	(b) (4), (b) (6)	12 Apr 2021 18:23:17

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:34:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:56:30
User entered '0'	(b) (4), (b) (6)	12 Apr 2021 18:23:17

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:34:29

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:56:30
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4)	12 Apr 2021 18:23:17

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:34:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:56:30
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 18:23:17

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:34:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:56:30
User entered 'No (N)'	(b) (4), (b) (6)	12 Apr 2021 18:23:17

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:34:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Apr 2021 18:23:17

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:34:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Apr 2021 18:23:17

US3172038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:34:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Apr 2021 18:23:17

US3172038

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:34:29

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:07:02
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered 'Yes (Y)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	27 Oct 2020 19:08:21
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	31 Aug 2020 19:03:33

US3172038

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:34:29

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:49:04
Signature has been broken.	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 20:08:54
User entered '01 Sep 2020' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 20:08:54
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered '1 Sep 2020'	Mariete Rendon (b) (4) (b) (4)	27 Oct 2020 19:08:46

US3172038

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:34:29

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered 'chest x-ray'	Mariete Rendon (b) (4) (b) (4)	27 Oct 2020 19:08:46

US3172038

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:34:29

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered 'Adverse Event (AE)'	Mariete Rendon (b) (4) (b) (4)	27 Oct 2020 19:08:46

US3172038

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:34:29

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered empty.	Mariete Rendon (b) (4) (b) (4)	27 Oct 2020 19:08:46

US3172038

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:34:29

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:25
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:49:04
Signature has been broken.	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 20:08:47
User entered '01 Sep 2020' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 20:08:47
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered '1 Sep 2020'	Mariete Rendon (b) (4) (b) (4)	27 Oct 2020 19:09:52

US3172038

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:34:29

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:25
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered 'ct chest, abdomen/pelvis'	Mariete Rendon (b) (4) (b) (4)	27 Oct 2020 19:09:52

US3172038

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:34:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:25
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered 'Adverse Event (AE)'	Mariete Rendon (b) (4) (b) (4)	27 Oct 2020 19:09:52

US3172038

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:34:29

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:25
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered empty.	Mariete Rendon (b) (4) (b) (4)	27 Oct 2020 19:09:52

US3172038

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:34:29

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:49:04
Signature has been broken.	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 20:08:38
User entered '01 Sep 2020' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 20:08:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered '1 Sep 2020'	Mariete Rendon (b) (4) (b) (4)	27 Oct 2020 19:10:06

US3172038

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:34:29

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered 'ct brain'	Mariete Rendon (b) (4) (b) (4)	27 Oct 2020 19:10:06

US3172038

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:34:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered 'Adverse Event (AE)'	Mariete Rendon (b) (4) (b) (4)	27 Oct 2020 19:10:06

US3172038

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:34:29

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered empty.	Mariete Rendon (b) (4) (b) (4)	27 Oct 2020 19:10:06

US3172038

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 15:34:29

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:32
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:49:04
Signature has been broken.	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 20:08:30
User entered '01 Sep 2020' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 20:08:30
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered '1 Sep 2020'	Mariete Rendon (b) (4) (b) (4)	27 Oct 2020 20:21:01

US3172038

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 15:34:29

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:32
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered 'right uretral stent placement'	Mariete Rendon (b) (4) (b) (4)	27 Oct 2020 20:21:01

US3172038

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 15:34:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:32
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered 'Adverse Event (AE)'	Mariete Rendon (b) (4) (b) (4)	27 Oct 2020 20:21:01

US3172038

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 15:34:29

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:32
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered empty.	Mariete Rendon (b) (4) (b) (4)	27 Oct 2020 20:21:01

US3172038

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 15:34:29

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:32:33
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered '01 Sep 2020'	Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:01:44

US3172038

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 15:34:29

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:32:33
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered 'Intubated'	Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:01:44

US3172038

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 15:34:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:32:33
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered 'Adverse Event (AE)'	Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:01:44

US3172038

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 15:34:29

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:32:33
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered empty.	Mariete Rendon (b) (4) (b) (4)	05 Jan 2021 21:01:44

US3172038

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 15:34:29

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:32:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:49:04
User entered '01 Sep 2020'	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 20:08:13

US3172038

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 15:34:29

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:32:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:49:04
User entered 'NEPHROSTOGRAM ANTEGRADE UROGRAPHY.'	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 20:08:13

US3172038

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 15:34:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:32:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:49:04
User entered 'Adverse Event (AE)'	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 20:08:13

US3172038

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 15:34:29

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:32:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:49:04
User entered empty.	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 20:08:13

US3172038

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 15:34:29

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:32:41
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:49:04
User entered '01 Sep 2020'	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 20:09:39

US3172038

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 15:34:29

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:32:41
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:49:04
User entered 'PERCUTANEOUS NEPHROSTOMY TUBE'	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 20:09:39

US3172038

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 15:34:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:32:41
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:49:04
User entered 'Adverse Event (AE)'	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 20:09:39

US3172038

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 15:34:29

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:32:41
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:49:04
User entered empty.	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 20:09:39

US3172038

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 15:34:29

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:32:44
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:49:04
User entered '01 Sep 2020'	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 20:10:18

US3172038

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 15:34:29

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:32:44
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:49:04
User entered 'SECONDARY HYDRONEPHOROSIS'	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 20:10:18

US3172038

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 15:34:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:32:44
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:49:04
User entered 'Adverse Event (AE)'	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 20:10:18

US3172038

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 15:34:29

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:32:44
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:49:04
User entered empty.	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 20:10:18

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 15:34:29

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:32:49
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:49:04
User entered '01 Sep 2020'	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 20:11:02

US3172038

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 15:34:29

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:32:49
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:49:04
User entered 'SCHEDULE A URETHOSCOPY' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 20:11:16
User entered 'SCHEDULE A URETHOSCOPY.'	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 20:11:02

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 15:34:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:32:49
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:49:04
User entered 'Adverse Event (AE)'	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 20:11:02

US3172038

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 15:34:29

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:32:49
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:49:04
User entered empty.	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 20:11:02

US3172038

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 15:34:29

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:32:52
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:56:30
User entered '01 Sep 2020'	(b) (4), (b) (6)	12 Apr 2021 18:28:30

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 15:34:29

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:32:52
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:56:30
User entered 'percutaneous nephrostomy'	(b) (4), (b) (6)	12 Apr 2021 18:28:30

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 15:34:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:32:52
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:56:30
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	12 Apr 2021 18:28:30

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 15:34:29

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:32:52
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 15:56:30
User entered empty.	(b) (4), (b) (6)	12 Apr 2021 18:28:30

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 09 Jun 2021 15:34:29

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '06 Apr 2021'	Jessie Downs (b) (4) (b) (4)	30 Apr 2021 19:36:51

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 09 Jun 2021 15:34:29

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User entered 'removed artery decompression device right ureter'	Jessie Downs (b) (4) (b) (4)	30 Apr 2021 19:36:51

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 09 Jun 2021 15:34:29

[Indication](#)

Audit	User	Time (GMT)
User entered 'Adverse Event (AE)'	Jessie Downs (b) (4) (b) (4)	30 Apr 2021 19:36:51

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 09 Jun 2021 15:34:29

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	30 Apr 2021 19:36:51

US3172038

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:34:29

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:25:03
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered '4 Sep 2020' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 14:00:16
User entered '16 Sep 2020'	Mariete Rendon (b) (4) (b) (4)	08 Oct 2020 13:47:36

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:34:29

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:25:03
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User closed query 'Per CDM: it appears all adverse event records have been removed yet it is recorded that reason for discontinuation is SAE. Please review and make all appropriate updates or clarify' (Site from DM).	(b) (4), (b) (6)	21 Nov 2020 13:25:39
Query 'Per CDM: it appears all adverse event records have been removed yet it is recorded that reason for discontinuation is SAE. Please review and make all appropriate updates or clarify' answered with 'pages were inactivated by CRA, Email sent to CRA for clarification.' (Site from DM).	Mariete Rendon (b) (4) (b) (4)	18 Nov 2020 20:51:29
User opened query 'Per CDM: it appears all adverse event records have been removed yet it is recorded that reason for discontinuation is SAE. Please review and make all appropriate updates or clarify' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 13:01:37
User closed query 'Per CDM: Primary reason for dosing discontinuation is recorded as SAE (specify). However in Visit 2 Day 29 (1) exposure form If No, reason not given is recorded as "Other(Missed visit)". Please review and update the data else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 03:26:47
Query 'Per CDM: Primary reason for dosing discontinuation is recorded as SAE (specify). However in Visit 2 Day 29 (1) exposure form If No, reason not given is recorded as "Other(Missed visit)". Please review and update the data else clarify. Thank you.' answered with 'Data was updated.' (Site from DM).	Jessie Downs (b) (4) (b) (4)	13 Nov 2020 17:56:40
User opened query 'Per CDM: Primary reason for dosing discontinuation is recorded as SAE (specify). However in Visit 2 Day 29 (1) exposure form If No, reason not given is recorded as "Other(Missed visit)". Please review and update the data else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 04:12:33
User entered 'SAE (specify) (SAE)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 14:00:16

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EAB) (1725)

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:34:29

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	Mariete Rendon (b) (4) (b) (4)	08 Oct 2020 13:47:36

US3172038

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:34:29

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 00:25:03
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User closed query 'Per CDM: Please update with SAE record number.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 12:20:52
Query 'Per CDM: Please update with SAE record number.' answered with 'Data updated' (Site from DM).	Mariete Rendon (b) (4) (b) (4)	23 Nov 2020 13:36:16
User entered 'SAE #2' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	23 Nov 2020 13:36:10
User opened query 'Per CDM: Please update with SAE record number.' (Site from DM).	(b) (4), (b) (6)	21 Nov 2020 13:28:41
User entered 'Withdrawal of due to SAE.' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 14:00:16
User entered 'MISSED VISIT'	Mariete Rendon (b) (4) (b) (4)	08 Oct 2020 13:47:36

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:34:29

Date of study discontinuation/completion (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:25:03
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	08 Dec 2020 03:10:13
Query 'Data is required. Please complete.' answered with 'Data entered in error.' (Site from System).	Mariete Rendon (b) (4) (b) (4)	04 Dec 2020 21:08:54
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Dec 2020 21:08:41
User entered empty; reason for change Data Entry Error	Mariete Rendon (b) (4) (b) (4)	04 Dec 2020 21:08:41
User entered '8 Sep 2020'	Mariete Rendon (b) (4) (b) (4)	04 Dec 2020 20:55:19

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:34:29

[Reason for discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:25:03
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	08 Dec 2020 03:10:15
Query 'Data is required. Please complete.' answered with 'Data entered in error.' (Site from System).	Mariete Rendon (b) (4) (b) (4)	04 Dec 2020 21:08:57
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Dec 2020 21:08:41
User entered empty; reason for change Data Entry Error	Mariete Rendon (b) (4) (b) (4)	04 Dec 2020 21:08:41
User entered 'SAE (specify) (SAE)'	Mariete Rendon (b) (4) (b) (4)	04 Dec 2020 20:55:19

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:34:29

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 00:25:03
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
User closed query 'Primary reason for dosing discontinuation is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is missing. Please provide.' (Site from System).	System	04 Dec 2020 21:08:41
User opened query 'Primary reason for dosing discontinuation is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is missing. Please provide.' (Site from System).	System	04 Dec 2020 20:55:19
User entered empty.	Mariete Rendon (b) (4)	04 Dec 2020 20:55:19
	(b) (4)	

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:34:29

If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:25:03
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered empty.	Mariete Rendon (b) (4) (b) (4)	04 Dec 2020 20:55:19

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:34:29

If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:25:03
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered empty.	Mariete Rendon (b) (4) (b) (4)	04 Dec 2020 20:55:19

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:34:29

Date of death (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:25:03
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered empty.	Mariete Rendon (b) (4) (b) (4)	04 Dec 2020 20:55:19

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:34:29

[Was autopsy performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:25:03
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
User entered empty.	Mariete Rendon (b) (4) (b) (4)	04 Dec 2020 20:55:19

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Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered		02 Sep 2020 23:59:02
'USA-US118-2020-MRNA-1273-P301000001'	System	

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'Yes (Y)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

Death

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'No (N)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
Un-reviewed for Safety.	System	09 Sep 2020 16:20:21
User entered 'Yes (Y)'	System	09 Sep 2020 16:20:21
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'No (N)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'Yes (Y)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'No (N)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'No (N)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'No (N)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 18:28:34
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:48:43
Amendment Manager: User entered 'Mark'	System	14 Sep 2020 21:48:43
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered empty.	System	09 Sep 2020 16:20:21
User entered 'Mark'	(b) (4), (b) (6)	03 Sep 2020 06:05:41

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 18:28:34
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:48:43
Amendment Manager: User entered 'Kutner'	System	14 Sep 2020 21:48:43
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered empty.	System	09 Sep 2020 16:20:21
User entered 'Kutner'	(b) (4), (b) (6)	03 Sep 2020 06:05:41

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered empty.	System	09 Sep 2020 16:20:21
User entered '2128 West Flagler street'	(b) (4), (b) (6)	03 Sep 2020 06:05:41

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4), (b) (6)	16 Feb 2021 15:04:52
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered empty.	System	09 Sep 2020 16:20:21
User entered 'suite 100'	(b) (4), (b) (6)	03 Sep 2020 06:05:41

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 18:28:34
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:48:43
Amendment Manager: User entered 'FL'	System	14 Sep 2020 21:48:43
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered empty.	System	09 Sep 2020 16:20:21
User entered 'Florida'	(b) (4), (b) (6)	03 Sep 2020 06:05:41

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered empty.	System	09 Sep 2020 16:20:21
User entered '33135'	(b) (4), (b) (6)	03 Sep 2020 06:05:41

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 06:28:47
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered 'US' (non-conformant).	System	03 Sep 2020 00:02:59

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:34:14
	(b) (4)	
Signature has been broken.	System	19 Feb 2021 19:40:57
User entered '13'	System	19 Feb 2021 19:40:57
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
User entered '12'	System	01 Feb 2021 20:23:16
User entered '11'	System	20 Nov 2020 17:24:21
User entered '10'	System	20 Nov 2020 15:59:47
User entered '9'	System	12 Nov 2020 21:29:11
User entered '8'	System	09 Nov 2020 15:53:30
User entered '7'	System	28 Oct 2020 13:25:57
User entered '6'	System	22 Oct 2020 21:39:01
User entered '5'	System	22 Oct 2020 19:17:51
User entered '4'	System	05 Oct 2020 14:09:37
User entered '3'	System	25 Sep 2020 18:14:47
User entered '2'	System	11 Sep 2020 00:12:56
User entered '1'	System	03 Sep 2020 00:02:59

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered	System	02 Sep 2020 23:59:02
'USA-US118-2020-MRNA-1273-P301000001'		

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'Yes (Y)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

Death

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'No (N)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
Un-reviewed for Safety.	System	09 Sep 2020 16:20:21
User entered 'Yes (Y)'	System	09 Sep 2020 16:20:21
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'No (N)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'Yes (Y)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'No (N)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'No (N)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'No (N)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 18:28:34
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:48:43
Amendment Manager: User entered 'Mark'	System	14 Sep 2020 21:48:43
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered empty.	System	09 Sep 2020 16:20:21
User entered 'Mark'	(b) (4), (b) (6)	03 Sep 2020 06:05:41

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 18:28:34
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:48:43
Amendment Manager: User entered 'Kutner'	System	14 Sep 2020 21:48:43
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered empty.	System	09 Sep 2020 16:20:21
User entered 'Kutner'	(b) (4), (b) (6)	03 Sep 2020 06:05:41

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered empty.	System	09 Sep 2020 16:20:21
User entered '2128 West Flagler street'	(b) (4), (b) (6)	03 Sep 2020 06:05:41

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered empty.	System	09 Sep 2020 16:20:21
User entered 'suite 100'	(b) (4), (b) (6)	03 Sep 2020 06:05:41

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 18:28:34
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:48:43
Amendment Manager: User entered 'FL'	System	14 Sep 2020 21:48:43
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered empty.	System	09 Sep 2020 16:20:21
User entered 'Florida'	(b) (4), (b) (6)	03 Sep 2020 06:05:41

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered empty.	System	09 Sep 2020 16:20:21
User entered '33135'	(b) (4), (b) (6)	03 Sep 2020 06:05:41

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 06:28:47
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered 'US' (non-conformant).	System	03 Sep 2020 00:02:59

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:34:14
	(b) (4)	
Signature has been broken.	System	19 Feb 2021 19:40:57
User entered '13'	System	19 Feb 2021 19:40:57
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
User entered '12'	System	01 Feb 2021 20:23:16
User entered '11'	System	20 Nov 2020 17:24:21
User entered '10'	System	20 Nov 2020 15:59:47
User entered '9'	System	12 Nov 2020 21:29:11
User entered '8'	System	09 Nov 2020 15:53:30
User entered '7'	System	28 Oct 2020 13:25:57
User entered '6'	System	22 Oct 2020 21:39:01
User entered '5'	System	22 Oct 2020 19:17:51
User entered '4'	System	05 Oct 2020 14:09:37
User entered '3'	System	25 Sep 2020 18:14:47
User entered '2'	System	11 Sep 2020 00:12:56
User entered '1'	System	03 Sep 2020 00:02:59

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:34:29

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
User entered '02/Sep/2020 20:02'	System	03 Sep 2020 00:02:59

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:34:29

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)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered 'I'	(b) (4), (b) (6)	03 Sep 2020 00:02:59

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered		02 Sep 2020 23:59:02
'USA-US118-2020-MRNA-1273-P301000001'	System	

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'Yes (Y)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'No (N)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
Un-reviewed for Safety.	System	09 Sep 2020 16:20:21
User entered 'Yes (Y)'	System	09 Sep 2020 16:20:21
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'No (N)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'Yes (Y)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'No (N)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'No (N)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'No (N)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 18:28:34
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:48:43
Amendment Manager: User entered 'Mark'	System	14 Sep 2020 21:48:43
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered empty.	System	09 Sep 2020 16:20:21
User entered 'Mark'	(b) (4), (b) (6)	03 Sep 2020 06:05:41

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 18:28:34
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:48:43
Amendment Manager: User entered 'Kutner'	System	14 Sep 2020 21:48:43
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered empty.	System	09 Sep 2020 16:20:21
User entered 'Kutner'	(b) (4), (b) (6)	03 Sep 2020 06:05:41

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered empty.	System	09 Sep 2020 16:20:21
User entered '2128 West Flagler street'	(b) (4), (b) (6)	03 Sep 2020 06:05:41

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered empty.	System	09 Sep 2020 16:20:21
User entered 'suite 100'	(b) (4), (b) (6)	03 Sep 2020 06:05:41

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 18:28:34
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:48:43
Amendment Manager: User entered 'FL'	System	14 Sep 2020 21:48:43
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered empty.	System	09 Sep 2020 16:20:21
User entered 'Florida'	(b) (4), (b) (6)	03 Sep 2020 06:05:41

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered empty.	System	09 Sep 2020 16:20:21
User entered '33135'	(b) (4), (b) (6)	03 Sep 2020 06:05:41

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 06:28:47
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered 'US' (non-conformant).	System	03 Sep 2020 00:02:59

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:34:14
	(b) (4)	
Signature has been broken.	System	19 Feb 2021 19:40:57
User entered '13'	System	19 Feb 2021 19:40:57
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
User entered '12'	System	01 Feb 2021 20:23:16
User entered '11'	System	20 Nov 2020 17:24:21
User entered '10'	System	20 Nov 2020 15:59:47
User entered '9'	System	12 Nov 2020 21:29:11
User entered '8'	System	09 Nov 2020 15:53:30
User entered '7'	System	28 Oct 2020 13:25:57
User entered '6'	System	22 Oct 2020 21:39:01
User entered '5'	System	22 Oct 2020 19:17:51
User entered '4'	System	05 Oct 2020 14:09:37
User entered '3'	System	25 Sep 2020 18:14:47
User entered '2'	System	11 Sep 2020 00:12:56
User entered '1'	System	03 Sep 2020 00:02:59

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:34:29

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
User entered '10/Sep/2020 20:12'	System	11 Sep 2020 00:12:56

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:34:29

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)	16 Feb 2021 15:04:52
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 18:28:34
User entered 'I'	(b) (4), (b) (6)	11 Sep 2020 00:12:56

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered	System	02 Sep 2020 23:59:02
'USA-US118-2020-MRNA-1273-P301000001'		

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'Yes (Y)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'No (N)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
Un-reviewed for Safety.	System	09 Sep 2020 16:20:21
User entered 'Yes (Y)'	System	09 Sep 2020 16:20:21
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'No (N)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'Yes (Y)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'No (N)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'No (N)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'No (N)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 18:28:34
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:48:43
Amendment Manager: User entered 'Mark'	System	14 Sep 2020 21:48:43
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered empty.	System	09 Sep 2020 16:20:21
User entered 'Mark'	(b) (4), (b) (6)	03 Sep 2020 06:05:41

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 18:28:34
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:48:43
Amendment Manager: User entered 'Kutner'	System	14 Sep 2020 21:48:43
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered empty.	System	09 Sep 2020 16:20:21
User entered 'Kutner'	(b) (4), (b) (6)	03 Sep 2020 06:05:41

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered empty.	System	09 Sep 2020 16:20:21
User entered '2128 West Flagler street'	(b) (4), (b) (6)	03 Sep 2020 06:05:41

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered empty.	System	09 Sep 2020 16:20:21
User entered 'suite 100'	(b) (4), (b) (6)	03 Sep 2020 06:05:41

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 18:28:34
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:48:43
Amendment Manager: User entered 'FL'	System	14 Sep 2020 21:48:43
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered empty.	System	09 Sep 2020 16:20:21
User entered 'Florida'	(b) (4), (b) (6)	03 Sep 2020 06:05:41

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered empty.	System	09 Sep 2020 16:20:21
User entered '33135'	(b) (4), (b) (6)	03 Sep 2020 06:05:41

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 06:28:47
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered 'US' (non-conformant).	System	03 Sep 2020 00:02:59

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:34:14
	(b) (4)	
Signature has been broken.	System	19 Feb 2021 19:40:57
User entered '13'	System	19 Feb 2021 19:40:57
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
User entered '12'	System	01 Feb 2021 20:23:16
User entered '11'	System	20 Nov 2020 17:24:21
User entered '10'	System	20 Nov 2020 15:59:47
User entered '9'	System	12 Nov 2020 21:29:11
User entered '8'	System	09 Nov 2020 15:53:30
User entered '7'	System	28 Oct 2020 13:25:57
User entered '6'	System	22 Oct 2020 21:39:01
User entered '5'	System	22 Oct 2020 19:17:51
User entered '4'	System	05 Oct 2020 14:09:37
User entered '3'	System	25 Sep 2020 18:14:47
User entered '2'	System	11 Sep 2020 00:12:56
User entered '1'	System	03 Sep 2020 00:02:59

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:34:29

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
User entered '25/Sep/2020 14:14'	System	25 Sep 2020 18:14:47

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:34:29

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)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 18:28:34
User entered 'I'	(b) (4), (b) (6)	25 Sep 2020 18:14:47

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered	System	02 Sep 2020 23:59:02
'USA-US118-2020-MRNA-1273-P301000001'		

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'Yes (Y)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

Death

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'No (N)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
Un-reviewed for Safety.	System	09 Sep 2020 16:20:21
User entered 'Yes (Y)'	System	09 Sep 2020 16:20:21
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'No (N)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'Yes (Y)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'No (N)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'No (N)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'No (N)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 18:28:34
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:48:43
Amendment Manager: User entered 'Mark'	System	14 Sep 2020 21:48:43
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered empty.	System	09 Sep 2020 16:20:21
User entered 'Mark'	(b) (4), (b) (6)	03 Sep 2020 06:05:41

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 18:28:34
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:48:43
Amendment Manager: User entered 'Kutner'	System	14 Sep 2020 21:48:43
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered empty.	System	09 Sep 2020 16:20:21
User entered 'Kutner'	(b) (4), (b) (6)	03 Sep 2020 06:05:41

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered empty.	System	09 Sep 2020 16:20:21
User entered '2128 West Flagler street'	(b) (4), (b) (6)	03 Sep 2020 06:05:41

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered empty.	System	09 Sep 2020 16:20:21
User entered 'suite 100'	(b) (4), (b) (6)	03 Sep 2020 06:05:41

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 18:28:34
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:48:43
Amendment Manager: User entered 'FL'	System	14 Sep 2020 21:48:43
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered empty.	System	09 Sep 2020 16:20:21
User entered 'Florida'	(b) (4), (b) (6)	03 Sep 2020 06:05:41

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered empty.	System	09 Sep 2020 16:20:21
User entered '33135'	(b) (4), (b) (6)	03 Sep 2020 06:05:41

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 06:28:47
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered 'US' (non-conformant).	System	03 Sep 2020 00:02:59

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:34:14
	(b) (4)	
Signature has been broken.	System	19 Feb 2021 19:40:57
User entered '13'	System	19 Feb 2021 19:40:57
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
User entered '12'	System	01 Feb 2021 20:23:16
User entered '11'	System	20 Nov 2020 17:24:21
User entered '10'	System	20 Nov 2020 15:59:47
User entered '9'	System	12 Nov 2020 21:29:11
User entered '8'	System	09 Nov 2020 15:53:30
User entered '7'	System	28 Oct 2020 13:25:57
User entered '6'	System	22 Oct 2020 21:39:01
User entered '5'	System	22 Oct 2020 19:17:51
User entered '4'	System	05 Oct 2020 14:09:37
User entered '3'	System	25 Sep 2020 18:14:47
User entered '2'	System	11 Sep 2020 00:12:56
User entered '1'	System	03 Sep 2020 00:02:59

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:34:29

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
User entered '05/Oct/2020 10:09'	System	05 Oct 2020 14:09:37

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:34:29

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)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 19:17:36
User entered 'I'	(b) (4), (b) (6)	05 Oct 2020 14:09:37

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered	System	02 Sep 2020 23:59:02
'USA-US118-2020-MRNA-1273-P301000001'		

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'Yes (Y)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

Death

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'No (N)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
Un-reviewed for Safety.	System	09 Sep 2020 16:20:21
User entered 'Yes (Y)'	System	09 Sep 2020 16:20:21
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'No (N)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'Yes (Y)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'No (N)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'No (N)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'No (N)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 18:28:34
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:48:43
Amendment Manager: User entered 'Mark'	System	14 Sep 2020 21:48:43
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered empty.	System	09 Sep 2020 16:20:21
User entered 'Mark'	(b) (4), (b) (6)	03 Sep 2020 06:05:41

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 18:28:34
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:48:43
Amendment Manager: User entered 'Kutner'	System	14 Sep 2020 21:48:43
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered empty.	System	09 Sep 2020 16:20:21
User entered 'Kutner'	(b) (4), (b) (6)	03 Sep 2020 06:05:41

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered empty.	System	09 Sep 2020 16:20:21
User entered '2128 West Flagler street'	(b) (4), (b) (6)	03 Sep 2020 06:05:41

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered empty.	System	09 Sep 2020 16:20:21
User entered 'suite 100'	(b) (4), (b) (6)	03 Sep 2020 06:05:41

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 18:28:34
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:48:43
Amendment Manager: User entered 'FL'	System	14 Sep 2020 21:48:43
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered empty.	System	09 Sep 2020 16:20:21
User entered 'Florida'	(b) (4), (b) (6)	03 Sep 2020 06:05:41

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered empty.	System	09 Sep 2020 16:20:21
User entered '33135'	(b) (4), (b) (6)	03 Sep 2020 06:05:41

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 06:28:47
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered 'US' (non-conformant).	System	03 Sep 2020 00:02:59

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:34:14
	(b) (4)	
Signature has been broken.	System	19 Feb 2021 19:40:57
User entered '13'	System	19 Feb 2021 19:40:57
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
User entered '12'	System	01 Feb 2021 20:23:16
User entered '11'	System	20 Nov 2020 17:24:21
User entered '10'	System	20 Nov 2020 15:59:47
User entered '9'	System	12 Nov 2020 21:29:11
User entered '8'	System	09 Nov 2020 15:53:30
User entered '7'	System	28 Oct 2020 13:25:57
User entered '6'	System	22 Oct 2020 21:39:01
User entered '5'	System	22 Oct 2020 19:17:51
User entered '4'	System	05 Oct 2020 14:09:37
User entered '3'	System	25 Sep 2020 18:14:47
User entered '2'	System	11 Sep 2020 00:12:56
User entered '1'	System	03 Sep 2020 00:02:59

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:34:29

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
User entered '22/Oct/2020 19:17'	System	22 Oct 2020 19:17:51

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:34:29

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)	16 Feb 2021 15:04:52
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 21:38:39
User entered 'I'	(b) (4), (b) (6)	22 Oct 2020 19:17:51

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered		
'USA-US118-2020-MRNA-1273-P301000001'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'Yes (Y)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

Death

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'No (N)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
Un-reviewed for Safety.	System	09 Sep 2020 16:20:21
User entered 'Yes (Y)'	System	09 Sep 2020 16:20:21
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'No (N)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'Yes (Y)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'No (N)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'No (N)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'No (N)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 18:28:34
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:48:43
Amendment Manager: User entered 'Mark'	System	14 Sep 2020 21:48:43
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered empty.	System	09 Sep 2020 16:20:21
User entered 'Mark'	(b) (4), (b) (6)	03 Sep 2020 06:05:41

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 18:28:34
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:48:43
Amendment Manager: User entered 'Kutner'	System	14 Sep 2020 21:48:43
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered empty.	System	09 Sep 2020 16:20:21
User entered 'Kutner'	(b) (4), (b) (6)	03 Sep 2020 06:05:41

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered empty.	System	09 Sep 2020 16:20:21
User entered '2128 West Flagler street'	(b) (4), (b) (6)	03 Sep 2020 06:05:41

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered empty.	System	09 Sep 2020 16:20:21
User entered 'suite 100'	(b) (4), (b) (6)	03 Sep 2020 06:05:41

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 18:28:34
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:48:43
Amendment Manager: User entered 'FL'	System	14 Sep 2020 21:48:43
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered empty.	System	09 Sep 2020 16:20:21
User entered 'Florida'	(b) (4), (b) (6)	03 Sep 2020 06:05:41

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered empty.	System	09 Sep 2020 16:20:21
User entered '33135'	(b) (4), (b) (6)	03 Sep 2020 06:05:41

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 06:28:47
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered 'US' (non-conformant).	System	03 Sep 2020 00:02:59

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:34:14
	(b) (4)	
Signature has been broken.	System	19 Feb 2021 19:40:57
User entered '13'	System	19 Feb 2021 19:40:57
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
User entered '12'	System	01 Feb 2021 20:23:16
User entered '11'	System	20 Nov 2020 17:24:21
User entered '10'	System	20 Nov 2020 15:59:47
User entered '9'	System	12 Nov 2020 21:29:11
User entered '8'	System	09 Nov 2020 15:53:30
User entered '7'	System	28 Oct 2020 13:25:57
User entered '6'	System	22 Oct 2020 21:39:01
User entered '5'	System	22 Oct 2020 19:17:51
User entered '4'	System	05 Oct 2020 14:09:37
User entered '3'	System	25 Sep 2020 18:14:47
User entered '2'	System	11 Sep 2020 00:12:56
User entered '1'	System	03 Sep 2020 00:02:59

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 15:34:29

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
User entered '22/Oct/2020 21:38'	System	22 Oct 2020 21:39:01

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 15:34:29

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)	16 Feb 2021 15:04:52
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:25:40
User entered 'I'	(b) (4), (b) (6)	22 Oct 2020 21:39:01

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered		02 Sep 2020 23:59:02
'USA-US118-2020-MRNA-1273-P301000001'	System	

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'Yes (Y)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

Death

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'No (N)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
Un-reviewed for Safety.	System	09 Sep 2020 16:20:21
User entered 'Yes (Y)'	System	09 Sep 2020 16:20:21
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'No (N)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'Yes (Y)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'No (N)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'No (N)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'No (N)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 18:28:34
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:48:43
Amendment Manager: User entered 'Mark'	System	14 Sep 2020 21:48:43
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered empty.	System	09 Sep 2020 16:20:21
User entered 'Mark'	(b) (4), (b) (6)	03 Sep 2020 06:05:41

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 18:28:34
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:48:43
Amendment Manager: User entered 'Kutner'	System	14 Sep 2020 21:48:43
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered empty.	System	09 Sep 2020 16:20:21
User entered 'Kutner'	(b) (4), (b) (6)	03 Sep 2020 06:05:41

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered empty.	System	09 Sep 2020 16:20:21
User entered '2128 West Flagler street'	(b) (4), (b) (6)	03 Sep 2020 06:05:41

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered empty.	System	09 Sep 2020 16:20:21
User entered 'suite 100'	(b) (4), (b) (6)	03 Sep 2020 06:05:41

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 18:28:34
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:48:43
Amendment Manager: User entered 'FL'	System	14 Sep 2020 21:48:43
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered empty.	System	09 Sep 2020 16:20:21
User entered 'Florida'	(b) (4), (b) (6)	03 Sep 2020 06:05:41

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered empty.	System	09 Sep 2020 16:20:21
User entered '33135'	(b) (4), (b) (6)	03 Sep 2020 06:05:41

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 06:28:47
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered 'US' (non-conformant).	System	03 Sep 2020 00:02:59

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:34:14
	(b) (4)	
Signature has been broken.	System	19 Feb 2021 19:40:57
User entered '13'	System	19 Feb 2021 19:40:57
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
User entered '12'	System	01 Feb 2021 20:23:16
User entered '11'	System	20 Nov 2020 17:24:21
User entered '10'	System	20 Nov 2020 15:59:47
User entered '9'	System	12 Nov 2020 21:29:11
User entered '8'	System	09 Nov 2020 15:53:30
User entered '7'	System	28 Oct 2020 13:25:57
User entered '6'	System	22 Oct 2020 21:39:01
User entered '5'	System	22 Oct 2020 19:17:51
User entered '4'	System	05 Oct 2020 14:09:37
User entered '3'	System	25 Sep 2020 18:14:47
User entered '2'	System	11 Sep 2020 00:12:56
User entered '1'	System	03 Sep 2020 00:02:59

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 15:34:29

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
User entered '28/Oct/2020 09:25'	System	28 Oct 2020 13:25:57

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 15:34:29

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)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 15:53:10
User entered 'I'	(b) (4), (b) (6)	28 Oct 2020 13:25:57

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered	System	02 Sep 2020 23:59:02
'USA-US118-2020-MRNA-1273-P301000001'		

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'Yes (Y)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'No (N)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
Un-reviewed for Safety.	System	09 Sep 2020 16:20:21
User entered 'Yes (Y)'	System	09 Sep 2020 16:20:21
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'No (N)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'Yes (Y)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'No (N)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'No (N)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'No (N)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 18:28:34
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:48:43
Amendment Manager: User entered 'Mark'	System	14 Sep 2020 21:48:43
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered empty.	System	09 Sep 2020 16:20:21
User entered 'Mark'	(b) (4), (b) (6)	03 Sep 2020 06:05:41

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 18:28:34
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:48:43
Amendment Manager: User entered 'Kutner'	System	14 Sep 2020 21:48:43
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered empty.	System	09 Sep 2020 16:20:21
User entered 'Kutner'	(b) (4), (b) (6)	03 Sep 2020 06:05:41

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered empty.	System	09 Sep 2020 16:20:21
User entered '2128 West Flagler street'	(b) (4), (b) (6)	03 Sep 2020 06:05:41

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered empty.	System	09 Sep 2020 16:20:21
User entered 'suite 100'	(b) (4), (b) (6)	03 Sep 2020 06:05:41

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 18:28:34
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:48:43
Amendment Manager: User entered 'FL'	System	14 Sep 2020 21:48:43
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered empty.	System	09 Sep 2020 16:20:21
User entered 'Florida'	(b) (4), (b) (6)	03 Sep 2020 06:05:41

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered empty.	System	09 Sep 2020 16:20:21
User entered '33135'	(b) (4), (b) (6)	03 Sep 2020 06:05:41

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 06:28:47
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered 'US' (non-conformant).	System	03 Sep 2020 00:02:59

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:34:14
	(b) (4)	
Signature has been broken.	System	19 Feb 2021 19:40:57
User entered '13'	System	19 Feb 2021 19:40:57
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
User entered '12'	System	01 Feb 2021 20:23:16
User entered '11'	System	20 Nov 2020 17:24:21
User entered '10'	System	20 Nov 2020 15:59:47
User entered '9'	System	12 Nov 2020 21:29:11
User entered '8'	System	09 Nov 2020 15:53:30
User entered '7'	System	28 Oct 2020 13:25:57
User entered '6'	System	22 Oct 2020 21:39:01
User entered '5'	System	22 Oct 2020 19:17:51
User entered '4'	System	05 Oct 2020 14:09:37
User entered '3'	System	25 Sep 2020 18:14:47
User entered '2'	System	11 Sep 2020 00:12:56
User entered '1'	System	03 Sep 2020 00:02:59

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 15:34:29

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
User entered '09/Nov/2020 15:53'	System	09 Nov 2020 15:53:30

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 15:34:29

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)	16 Feb 2021 15:04:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 21:29:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
User entered 'I'	(b) (4), (b) (6)	09 Nov 2020 15:53:30

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered		02 Sep 2020 23:59:02
'USA-US118-2020-MRNA-1273-P301000001'	System	

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'Yes (Y)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

Death

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'No (N)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
Un-reviewed for Safety.	System	09 Sep 2020 16:20:21
User entered 'Yes (Y)'	System	09 Sep 2020 16:20:21
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'No (N)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'Yes (Y)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'No (N)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'No (N)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'No (N)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 18:28:34
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:48:43
Amendment Manager: User entered 'Mark'	System	14 Sep 2020 21:48:43
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered empty.	System	09 Sep 2020 16:20:21
User entered 'Mark'	(b) (4), (b) (6)	03 Sep 2020 06:05:41

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 18:28:34
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:48:43
Amendment Manager: User entered 'Kutner'	System	14 Sep 2020 21:48:43
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered empty.	System	09 Sep 2020 16:20:21
User entered 'Kutner'	(b) (4), (b) (6)	03 Sep 2020 06:05:41

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered empty.	System	09 Sep 2020 16:20:21
User entered '2128 West Flagler street'	(b) (4), (b) (6)	03 Sep 2020 06:05:41

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered empty.	System	09 Sep 2020 16:20:21
User entered 'suite 100'	(b) (4), (b) (6)	03 Sep 2020 06:05:41

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 18:28:34
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:48:43
Amendment Manager: User entered 'FL'	System	14 Sep 2020 21:48:43
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered empty.	System	09 Sep 2020 16:20:21
User entered 'Florida'	(b) (4), (b) (6)	03 Sep 2020 06:05:41

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered empty.	System	09 Sep 2020 16:20:21
User entered '33135'	(b) (4), (b) (6)	03 Sep 2020 06:05:41

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 06:28:47
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered 'US' (non-conformant).	System	03 Sep 2020 00:02:59

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:34:14
	(b) (4)	
Signature has been broken.	System	19 Feb 2021 19:40:57
User entered '13'	System	19 Feb 2021 19:40:57
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
User entered '12'	System	01 Feb 2021 20:23:16
User entered '11'	System	20 Nov 2020 17:24:21
User entered '10'	System	20 Nov 2020 15:59:47
User entered '9'	System	12 Nov 2020 21:29:11
User entered '8'	System	09 Nov 2020 15:53:30
User entered '7'	System	28 Oct 2020 13:25:57
User entered '6'	System	22 Oct 2020 21:39:01
User entered '5'	System	22 Oct 2020 19:17:51
User entered '4'	System	05 Oct 2020 14:09:37
User entered '3'	System	25 Sep 2020 18:14:47
User entered '2'	System	11 Sep 2020 00:12:56
User entered '1'	System	03 Sep 2020 00:02:59

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form (9)

Generated On: 09 Jun 2021 15:34:29

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
User entered '12/Nov/2020 21:29'	System	12 Nov 2020 21:29:11

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form (9)

Generated On: 09 Jun 2021 15:34:29

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)	16 Feb 2021 15:04:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 15:59:07
User entered 'I'	(b) (4), (b) (6)	12 Nov 2020 21:29:11

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered		
'USA-US118-2020-MRNA-1273-P301000001'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'Yes (Y)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

Death

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'No (N)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
Un-reviewed for Safety.	System	09 Sep 2020 16:20:21
User entered 'Yes (Y)'	System	09 Sep 2020 16:20:21
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'No (N)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'Yes (Y)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'No (N)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'No (N)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'No (N)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 18:28:34
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:48:43
Amendment Manager: User entered 'Mark'	System	14 Sep 2020 21:48:43
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered empty.	System	09 Sep 2020 16:20:21
User entered 'Mark'	(b) (4), (b) (6)	03 Sep 2020 06:05:41

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 18:28:34
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:48:43
Amendment Manager: User entered 'Kutner'	System	14 Sep 2020 21:48:43
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered empty.	System	09 Sep 2020 16:20:21
User entered 'Kutner'	(b) (4), (b) (6)	03 Sep 2020 06:05:41

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered empty.	System	09 Sep 2020 16:20:21
User entered '2128 West Flagler street'	(b) (4), (b) (6)	03 Sep 2020 06:05:41

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered empty.	System	09 Sep 2020 16:20:21
User entered 'suite 100'	(b) (4), (b) (6)	03 Sep 2020 06:05:41

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 18:28:34
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:48:43
Amendment Manager: User entered 'FL'	System	14 Sep 2020 21:48:43
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered empty.	System	09 Sep 2020 16:20:21
User entered 'Florida'	(b) (4), (b) (6)	03 Sep 2020 06:05:41

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered empty.	System	09 Sep 2020 16:20:21
User entered '33135'	(b) (4), (b) (6)	03 Sep 2020 06:05:41

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 06:28:47
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered 'US' (non-conformant).	System	03 Sep 2020 00:02:59

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:34:14
	(b) (4)	
Signature has been broken.	System	19 Feb 2021 19:40:57
User entered '13'	System	19 Feb 2021 19:40:57
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
User entered '12'	System	01 Feb 2021 20:23:16
User entered '11'	System	20 Nov 2020 17:24:21
User entered '10'	System	20 Nov 2020 15:59:47
User entered '9'	System	12 Nov 2020 21:29:11
User entered '8'	System	09 Nov 2020 15:53:30
User entered '7'	System	28 Oct 2020 13:25:57
User entered '6'	System	22 Oct 2020 21:39:01
User entered '5'	System	22 Oct 2020 19:17:51
User entered '4'	System	05 Oct 2020 14:09:37
User entered '3'	System	25 Sep 2020 18:14:47
User entered '2'	System	11 Sep 2020 00:12:56
User entered '1'	System	03 Sep 2020 00:02:59

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form (10)

Generated On: 09 Jun 2021 15:34:29

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
User entered '20/Nov/2020 10:59'	System	20 Nov 2020 15:59:47

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form (10)

Generated On: 09 Jun 2021 15:34:29

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)	16 Feb 2021 15:04:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 17:23:58
User entered 'I'	(b) (4), (b) (6)	20 Nov 2020 15:59:47

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered		02 Sep 2020 23:59:02
'USA-US118-2020-MRNA-1273-P301000001'	System	

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'Yes (Y)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

Death

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'No (N)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
Un-reviewed for Safety.	System	09 Sep 2020 16:20:21
User entered 'Yes (Y)'	System	09 Sep 2020 16:20:21
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'No (N)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'Yes (Y)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'No (N)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'No (N)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'No (N)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 18:28:34
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:48:43
Amendment Manager: User entered 'Mark'	System	14 Sep 2020 21:48:43
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered empty.	System	09 Sep 2020 16:20:21
User entered 'Mark'	(b) (4), (b) (6)	03 Sep 2020 06:05:41

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 18:28:34
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:48:43
Amendment Manager: User entered 'Kutner'	System	14 Sep 2020 21:48:43
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered empty.	System	09 Sep 2020 16:20:21
User entered 'Kutner'	(b) (4), (b) (6)	03 Sep 2020 06:05:41

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered empty.	System	09 Sep 2020 16:20:21
User entered '2128 West Flagler street'	(b) (4), (b) (6)	03 Sep 2020 06:05:41

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered empty.	System	09 Sep 2020 16:20:21
User entered 'suite 100'	(b) (4), (b) (6)	03 Sep 2020 06:05:41

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 18:28:34
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:48:43
Amendment Manager: User entered 'FL'	System	14 Sep 2020 21:48:43
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered empty.	System	09 Sep 2020 16:20:21
User entered 'Florida'	(b) (4), (b) (6)	03 Sep 2020 06:05:41

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered empty.	System	09 Sep 2020 16:20:21
User entered '33135'	(b) (4), (b) (6)	03 Sep 2020 06:05:41

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 06:28:47
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered 'US' (non-conformant).	System	03 Sep 2020 00:02:59

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:34:14
	(b) (4)	
Signature has been broken.	System	19 Feb 2021 19:40:57
User entered '13'	System	19 Feb 2021 19:40:57
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
User entered '12'	System	01 Feb 2021 20:23:16
User entered '11'	System	20 Nov 2020 17:24:21
User entered '10'	System	20 Nov 2020 15:59:47
User entered '9'	System	12 Nov 2020 21:29:11
User entered '8'	System	09 Nov 2020 15:53:30
User entered '7'	System	28 Oct 2020 13:25:57
User entered '6'	System	22 Oct 2020 21:39:01
User entered '5'	System	22 Oct 2020 19:17:51
User entered '4'	System	05 Oct 2020 14:09:37
User entered '3'	System	25 Sep 2020 18:14:47
User entered '2'	System	11 Sep 2020 00:12:56
User entered '1'	System	03 Sep 2020 00:02:59

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form (11)

Generated On: 09 Jun 2021 15:34:29

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
User entered '20/Nov/2020 12:24'	System	20 Nov 2020 17:24:21

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form (11)

Generated On: 09 Jun 2021 15:34:29

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)	16 Feb 2021 15:04:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 20:23:20
User entered 'I'	(b) (4), (b) (6)	20 Nov 2020 17:24:21

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered		02 Sep 2020 23:59:02
'USA-US118-2020-MRNA-1273-P301000001'	System	

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'Yes (Y)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

Death

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'No (N)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
Un-reviewed for Safety.	System	09 Sep 2020 16:20:21
User entered 'Yes (Y)'	System	09 Sep 2020 16:20:21
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'No (N)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'Yes (Y)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'No (N)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'No (N)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'No (N)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 18:28:34
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:48:43
Amendment Manager: User entered 'Mark'	System	14 Sep 2020 21:48:43
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered empty.	System	09 Sep 2020 16:20:21
User entered 'Mark'	(b) (4), (b) (6)	03 Sep 2020 06:05:41

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 18:28:34
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:48:43
Amendment Manager: User entered 'Kutner'	System	14 Sep 2020 21:48:43
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered empty.	System	09 Sep 2020 16:20:21
User entered 'Kutner'	(b) (4), (b) (6)	03 Sep 2020 06:05:41

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered empty.	System	09 Sep 2020 16:20:21
User entered '2128 West Flagler street'	(b) (4), (b) (6)	03 Sep 2020 06:05:41

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered empty.	System	09 Sep 2020 16:20:21
User entered 'suite 100'	(b) (4), (b) (6)	03 Sep 2020 06:05:41

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 18:28:34
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:48:43
Amendment Manager: User entered 'FL'	System	14 Sep 2020 21:48:43
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered empty.	System	09 Sep 2020 16:20:21
User entered 'Florida'	(b) (4), (b) (6)	03 Sep 2020 06:05:41

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered empty.	System	09 Sep 2020 16:20:21
User entered '33135'	(b) (4), (b) (6)	03 Sep 2020 06:05:41

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 06:28:47
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered 'US' (non-conformant).	System	03 Sep 2020 00:02:59

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:34:14
	(b) (4)	
Signature has been broken.	System	19 Feb 2021 19:40:57
User entered '13'	System	19 Feb 2021 19:40:57
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
User entered '12'	System	01 Feb 2021 20:23:16
User entered '11'	System	20 Nov 2020 17:24:21
User entered '10'	System	20 Nov 2020 15:59:47
User entered '9'	System	12 Nov 2020 21:29:11
User entered '8'	System	09 Nov 2020 15:53:30
User entered '7'	System	28 Oct 2020 13:25:57
User entered '6'	System	22 Oct 2020 21:39:01
User entered '5'	System	22 Oct 2020 19:17:51
User entered '4'	System	05 Oct 2020 14:09:37
User entered '3'	System	25 Sep 2020 18:14:47
User entered '2'	System	11 Sep 2020 00:12:56
User entered '1'	System	03 Sep 2020 00:02:59

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form (12)

Generated On: 09 Jun 2021 15:34:29

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
User entered '01/Feb/2021 15:23'	System	01 Feb 2021 20:23:16

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form (12)

Generated On: 09 Jun 2021 15:34:29

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)	16 Feb 2021 15:04:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 20:23:20
User entered 'I'	(b) (4), (b) (6)	01 Feb 2021 20:23:16

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered	System	02 Sep 2020 23:59:02
'USA-US118-2020-MRNA-1273-P301000001'		

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'Yes (Y)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

Death

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'No (N)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
Un-reviewed for Safety.	System	09 Sep 2020 16:20:21
User entered 'Yes (Y)'	System	09 Sep 2020 16:20:21
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'No (N)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'Yes (Y)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'No (N)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'No (N)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	03 Sep 2020 00:02:53
User entered 'No (N)'	System	02 Sep 2020 23:59:02

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 18:28:34
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:48:43
Amendment Manager: User entered 'Mark'	System	14 Sep 2020 21:48:43
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered empty.	System	09 Sep 2020 16:20:21
User entered 'Mark'	(b) (4), (b) (6)	03 Sep 2020 06:05:41

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 18:28:34
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:48:43
Amendment Manager: User entered 'Kutner'	System	14 Sep 2020 21:48:43
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered empty.	System	09 Sep 2020 16:20:21
User entered 'Kutner'	(b) (4), (b) (6)	03 Sep 2020 06:05:41

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered empty.	System	09 Sep 2020 16:20:21
User entered '2128 West Flagler street'	(b) (4), (b) (6)	03 Sep 2020 06:05:41

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered empty.	System	09 Sep 2020 16:20:21
User entered 'suite 100'	(b) (4), (b) (6)	03 Sep 2020 06:05:41

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 18:28:34
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:48:43
Amendment Manager: User entered 'FL'	System	14 Sep 2020 21:48:43
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered empty.	System	09 Sep 2020 16:20:21
User entered 'Florida'	(b) (4), (b) (6)	03 Sep 2020 06:05:41

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:04:52
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered empty.	System	09 Sep 2020 16:20:21
User entered '33135'	(b) (4), (b) (6)	03 Sep 2020 06:05:41

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:45
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 06:28:47
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:12:43
User entered 'US' (non-conformant).	System	03 Sep 2020 00:02:59

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:29

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:34:14
	(b) (4)	
Signature has been broken.	System	19 Feb 2021 19:40:57
User entered '13'	System	19 Feb 2021 19:40:57
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:04:52
	(b) (4)	
User entered '12'	System	01 Feb 2021 20:23:16
User entered '11'	System	20 Nov 2020 17:24:21
User entered '10'	System	20 Nov 2020 15:59:47
User entered '9'	System	12 Nov 2020 21:29:11
User entered '8'	System	09 Nov 2020 15:53:30
User entered '7'	System	28 Oct 2020 13:25:57
User entered '6'	System	22 Oct 2020 21:39:01
User entered '5'	System	22 Oct 2020 19:17:51
User entered '4'	System	05 Oct 2020 14:09:37
User entered '3'	System	25 Sep 2020 18:14:47
User entered '2'	System	11 Sep 2020 00:12:56
User entered '1'	System	03 Sep 2020 00:02:59

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form (13)

Generated On: 09 Jun 2021 15:34:29

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:34:14
	(b) (4)	
User entered '19/Feb/2021 14:40'	System	19 Feb 2021 19:40:57

US3172038

Folder: SAE USA-US118-2020-MRNA-1273-P301000001

Form: Safety Report Form (13)

Generated On: 09 Jun 2021 15:34:29

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)	23 Feb 2021 14:34:14
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 19:41:01
User entered 'I'	(b) (4), (b) (6)	19 Feb 2021 19:40:57