

US3272260 (Prod: Meridian Clinical Research (Grand Island, Nebraska))

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:16:35

All time stamps listed in this document are displayed in GMT

US3272260

Form: Participant Creation

Data signed: (b) (4) 29 Apr 2021 23:23:52

Generated On: 11 Aug 2021 22:16:35

Participant ID

US3272260

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

US3272260

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 14 Apr 2021 19:03:12

Generated On: 11 Aug 2021 22:16:35

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	22 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 14 Apr 2021 19:03:12

Generated On: 11 Aug 2021 22:16:35

Date of Birth (MMM yyyy)	(b) (6) 1989
Age	30
Age Units	YEARS
Age (Derived)	30
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 14 Apr 2021 19:03:12

Generated On: 11 Aug 2021 22:16:35

Date of Informed Consent (<i>dd MMM yyyy</i>)	22 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input checked="" type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 14 Apr 2021 19:03:12

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 14 Apr 2021 19:03:12

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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) 14 Apr 2021 19:03:12

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Condition	EXERCISE INDUCED ASTHMA
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 14 Apr 2021 19:03:12

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Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 AUG 2020
Time of assessment (00:00-23:59)	08:45 (24 HR)
Vital Signs Date and Time (derived)	22 AUG 2020 08:45
Height (xxx.x)	188 cm
Weight (xxx.x)	134.1 kg
BMI (xxx.x)	37.94138 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 14 Apr 2021 19:03:12

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 14 Apr 2021 19:03:12

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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) 14 Apr 2021 19:03:12

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 29 Apr 2021 23:24:25

Generated On: 11 Aug 2021 22:16:35

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

Visit date (dd MMM yyyy)	22 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) 29 Apr 2021 23:24:25

Generated On: 11 Aug 2021 22:16:35

What was the date of randomization? (dd MMM yyyy) 22 AUG 2020

What was the participant's randomization number? 107401

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 29 Apr 2021 23:24:25

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Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 29 Apr 2021 23:24:25

Generated On: 11 Aug 2021 22:16:35

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)	22 AUG 2020
Time of assessment (00:00-23:59)	08:45 (24 HR)
Vital Signs Date and Time (derived)	22 AUG 2020 08:45
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	98 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 29 Apr 2021 23:24:25

Generated On: 11 Aug 2021 22:16:35

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 AUG 2020
Time of assessment (00:00-23:59)	10:28 (24 HR)
Vital Signs Date and Time (derived)	22 AUG 2020 10:28
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	24 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 29 Apr 2021 23:24:25

Generated On: 11 Aug 2021 22:16:35

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 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) 29 Apr 2021 23:24:25

Generated On: 11 Aug 2021 22:16:35

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) 22 AUG 2020

What was the treatment time? (00:00-23:59) 09:57 (24 HR)

Treatment Date and Time (derived) 22 AUG 2020 09:57

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) 29 Apr 2021 23:24:25

Generated On: 11 Aug 2021 22:16:35

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

22 AUG 2020

Collection time (00:00-23:59)

09:20 (24 HR)

Collection date and time (derived)

22 AUG 2020 09:20

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 29 Apr 2021 23:24:25

Generated On: 11 Aug 2021 22:16:35

Collection date (dd MMM yyyy)			22 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:13	22 AUG 2020 09:13
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 23:24:25

Generated On: 11 Aug 2021 22:16:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 AUG 2020 10:27

PC Open Date & Time

22 AUG 2020 10:17

PC Close Date & Time

22 AUG 2020 12:47

US3272260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐
No ☒

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

PC Time Stamp	22 AUG 2020 23:23
PC Open Date & Time	22 AUG 2020 13:42
PC Close Date & Time	23 AUG 2020 11:59

US3272260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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

23 AUG 2020 22:53

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3272260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 AUG 2020 22:26

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3272260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:16:35

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

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 AUG 2020 21:21

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3272260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:16:35

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

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 AUG 2020 22:11

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3272260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 AUG 2020 21:36

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3272260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:16:35

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

97.7 °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

28 AUG 2020 21:10

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3272260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:16:35

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

22 AUG 2020 10:20

PC Open Date & Time

22 AUG 2020 10:17

PC Close Date & Time

22 AUG 2020 12:47

US3272260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:16:35

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

22 AUG 2020 23:24

PC Open Date & Time

22 AUG 2020 13:42

PC Close Date & Time

23 AUG 2020 11:59

US3272260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:16:35

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

23 AUG 2020 22:54

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3272260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:16:35

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

24 AUG 2020 22:27

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3272260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:16:35

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

25 AUG 2020 21:22

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3272260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:16:35

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

26 AUG 2020 22:12

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3272260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:16:35

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

27 AUG 2020 21:37

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3272260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:16:35

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

28 AUG 2020 21:09

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:16:35

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 ☐

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:16:35

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

No ☒

Yes ☐

PC Time stamp	22 AUG 2020 10:19
PC Open Date & Time	22 AUG 2020 10:17
PC Close Date & Time	22 AUG 2020 12:47

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:16:35

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 ☐

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:16:35

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

No ☒

Yes ☐

PC Time stamp	22 AUG 2020 23:24
PC Open Date & Time	22 AUG 2020 13:42
PC Close Date & Time	23 AUG 2020 11:59

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:16:35

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)

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:16:35

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 22:55
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:16:35

Yes <input type="checkbox"/>	
PC Time stamp	24 AUG 2020 22:27
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:16:35

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 ☒

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:16:35

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 21:22
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:16:35

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 ☒

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:16:35

Yes <input type="checkbox"/>	
PC Time stamp	26 AUG 2020 22:12
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:16:35

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 ☒

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:16:35

Yes <input type="checkbox"/>	
PC Time stamp	27 AUG 2020 21:37
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:16:35

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 ☐

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EAB) (1725)

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:16:35

		Yes <input type="checkbox"/>
PC Time stamp	28 AUG 2020 21:10	
PC Open Date & Time	28 AUG 2020 12:00	
PC Close Date & Time	29 AUG 2020 11:59	

US3272260

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 23:23:54

Generated On: 11 Aug 2021 22:16:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3272260

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 23:23:54

Generated On: 11 Aug 2021 22:16:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272260

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 23:23:54

Generated On: 11 Aug 2021 22:16:35

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 8 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3272260

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 23:23:54

Generated On: 11 Aug 2021 22:16:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272260

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 23:23:54

Generated On: 11 Aug 2021 22:16:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3272260

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 23:23:54

Generated On: 11 Aug 2021 22:16:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272260

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 29 Apr 2021 23:24:25

Generated On: 11 Aug 2021 22:16:35

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

Visit date (dd MMM yyyy)	23 SEP 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	VISIT2
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US3272260

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 29 Apr 2021 23:24:25

Generated On: 11 Aug 2021 22:16:35

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)	23 SEP 2020
Time of assessment (00:00-23:59)	13:16 (24 HR)
Vital Signs Date and Time (derived)	23 SEP 2020 13:16
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG

US3272260

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 29 Apr 2021 23:24:25

Generated On: 11 Aug 2021 22:16:35

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" 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	

US3272260

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Apr 2021 23:24:25

Generated On: 11 Aug 2021 22:16:35

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 SEP 2020

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

US3272260

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 29 Apr 2021 23:24:25

Generated On: 11 Aug 2021 22:16:35

Was study treatment given? Yes ☐
No ☒

If No, reason not given

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

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

What was the study treatment?

What was the treatment date? (dd MMM yyyy)

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

Treatment Date and Time (derived)

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

What was the frequency of the study treatment dosing?

What was the route of administration for the study treatment?

US3272260

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Apr 2021 23:24:25

Generated On: 11 Aug 2021 22:16:35

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

23 SEP 2020

Collection time (00:00-23:59)

13:43 (24 HR)

Collection date and time (derived)

23 SEP 2020 13:43

US3272260

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 29 Apr 2021 23:24:25

Generated On: 11 Aug 2021 22:16:35

Collection date (dd MMM yyyy)			23 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:53	23 SEP 2020 13:53
Nasopharyngeal Swab 2	No		

US3272260

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 23:24:25

Generated On: 11 Aug 2021 22:16:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272260

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 23:23:54

Generated On: 11 Aug 2021 22:16:35

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3272260

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 23:23:54

Generated On: 11 Aug 2021 22:16:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272260

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 23:23:54

Generated On: 11 Aug 2021 22:16:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

07 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3272260

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 23:23:54

Generated On: 11 Aug 2021 22:16:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272260

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 23:23:54

Generated On: 11 Aug 2021 22:16:35

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 14 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3272260

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 23:23:54

Generated On: 11 Aug 2021 22:16:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272260

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 29 Apr 2021 23:24:25

Generated On: 11 Aug 2021 22:16:35

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3272260

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 29 Apr 2021 23:24:25

Generated On: 11 Aug 2021 22:16:35

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	21 OCT 2020
Time of assessment (00:00-23:59)	14:38 (24 HR)
Vital Signs Date and Time (derived)	21 OCT 2020 14:38
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)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	93 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3272260

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Apr 2021 23:24:25

Generated On: 11 Aug 2021 22:16:35

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 OCT 2020

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

US3272260

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Apr 2021 23:24:25

Generated On: 11 Aug 2021 22:16:35

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

21 OCT 2020

Collection time (00:00-23:59)

14:43 (24 HR)

Collection date and time (derived)

21 OCT 2020 14:43

US3272260

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 23:24:25

Generated On: 11 Aug 2021 22:16:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272260

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 OCT 2020 15:54:55
Patient Cloud Open Date & Time	22 OCT 2020 00:01
Patient Cloud Close Date & Time	26 OCT 2020 23:59

US3272260

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

31 OCT 2020 12:32:18

Patient Cloud Open Date & Time

29 OCT 2020 00:01

Patient Cloud Close Date & Time

02 NOV 2020 23:59

US3272260

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 NOV 2020 13:46:37
Patient Cloud Open Date & Time	05 NOV 2020 00:01
Patient Cloud Close Date & Time	09 NOV 2020 23:59

US3272260

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3272260

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 NOV 2020 07:45:44
Patient Cloud Open Date & Time	23 NOV 2020 00:01
Patient Cloud Close Date & Time	27 NOV 2020 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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="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"/>

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

[Patient Cloud Open Date & Time](#)

30 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

04 DEC 2020 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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="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"/>

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

[Patient Cloud Open Date & Time](#)

07 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

11 DEC 2020 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

15 DEC 2020 17:14:33

Patient Cloud Open Date & Time

14 DEC 2020 00:01

Patient Cloud Close Date & Time

18 DEC 2020 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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	21 DEC 2020 06:35:01
Patient Cloud Open Date & Time	21 DEC 2020 00:01
Patient Cloud Close Date & Time	25 DEC 2020 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 DEC 2020 16:01:00

Patient Cloud Open Date & Time

28 DEC 2020 00:01

Patient Cloud Close Date & Time

01 JAN 2021 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 JAN 2021 09:48:54

Patient Cloud Open Date & Time

04 JAN 2021 00:01

Patient Cloud Close Date & Time

08 JAN 2021 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 JAN 2021 09:59:18
Patient Cloud Open Date & Time	11 JAN 2021 00:01
Patient Cloud Close Date & Time	15 JAN 2021 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 JAN 2021 16:57:06

Patient Cloud Open Date & Time

18 JAN 2021 00:01

Patient Cloud Close Date & Time

22 JAN 2021 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 JAN 2021 17:48:53

Patient Cloud Open Date & Time

25 JAN 2021 00:01

Patient Cloud Close Date & Time

29 JAN 2021 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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 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 FEB 2021 18:01:20
Patient Cloud Open Date & Time	01 FEB 2021 00:01
Patient Cloud Close Date & Time	05 FEB 2021 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 FEB 2021 18:04:40

Patient Cloud Open Date & Time

08 FEB 2021 00:01

Patient Cloud Close Date & Time

12 FEB 2021 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 FEB 2021 12:00:39
Patient Cloud Open Date & Time	15 FEB 2021 00:01
Patient Cloud Close Date & Time	19 FEB 2021 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 FEB 2021 23:41:05

Patient Cloud Open Date & Time

22 FEB 2021 00:01

Patient Cloud Close Date & Time

26 FEB 2021 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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 checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	01 MAR 2021 18:45:05
Patient Cloud Open Date & Time	01 MAR 2021 00:01
Patient Cloud Close Date & Time	05 MAR 2021 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

12 MAR 2021 08:49:54

Patient Cloud Open Date & Time

08 MAR 2021 00:01

Patient Cloud Close Date & Time

12 MAR 2021 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

17 MAR 2021 08:58:10

Patient Cloud Open Date & Time

15 MAR 2021 00:01

Patient Cloud Close Date & Time

19 MAR 2021 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

22 MAR 2021 10:11:56

Patient Cloud Open Date & Time

22 MAR 2021 00:01

Patient Cloud Close Date & Time

26 MAR 2021 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

29 MAR 2021 06:25:12

Patient Cloud Open Date & Time

29 MAR 2021 00:01

Patient Cloud Close Date & Time

02 APR 2021 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

Patient Cloud Close Date & Time

09 APR 2021 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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	16 APR 2021 10:02:57
Patient Cloud Open Date & Time	12 APR 2021 00:01
Patient Cloud Close Date & Time	16 APR 2021 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

21 APR 2021 22:24:37

Patient Cloud Open Date & Time

19 APR 2021 00:01

Patient Cloud Close Date & Time

23 APR 2021 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

26 APR 2021 20:33:43

Patient Cloud Open Date & Time

26 APR 2021 00:01

Patient Cloud Close Date & Time

30 APR 2021 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

03 MAY 2021 00:02:40

Patient Cloud Open Date & Time

03 MAY 2021 00:01

Patient Cloud Close Date & Time

07 MAY 2021 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

Patient Cloud Close Date & Time

14 MAY 2021 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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="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"/>

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

Patient Cloud Close Date & Time

21 MAY 2021 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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"/>

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

Patient Cloud Close Date & Time

28 MAY 2021 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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°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"/>

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

Patient Cloud Close Date & Time

04 JUN 2021 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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="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"/>

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

Patient Cloud Close Date & Time

11 JUN 2021 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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="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"/>

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

Patient Cloud Close Date & Time

18 JUN 2021 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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"/>

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

Patient Cloud Close Date & Time

25 JUN 2021 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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="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"/>

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

Patient Cloud Close Date & Time

02 JUL 2021 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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"/>

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

Patient Cloud Close Date & Time

09 JUL 2021 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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"/>

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

Patient Cloud Close Date & Time

16 JUL 2021 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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"/>

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

Patient Cloud Close Date & Time

23 JUL 2021 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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="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"/>

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

Patient Cloud Close Date & Time

30 JUL 2021 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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"/>

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

Patient Cloud Close Date & Time

06 AUG 2021 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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="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"/>

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

Patient Cloud Close Date & Time

13 AUG 2021 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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"/>

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

Patient Cloud Close Date & Time

20 AUG 2021 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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"/>

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

Patient Cloud Close Date & Time

27 AUG 2021 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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="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"/>

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

Patient Cloud Close Date & Time

03 SEP 2021 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT	DAY 383
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

Patient Cloud Close Date & Time

10 SEP 2021 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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="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"/>

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

Patient Cloud Close Date & Time

17 SEP 2021 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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°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"/>

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

Patient Cloud Close Date & Time

24 SEP 2021 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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°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"/>

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

Patient Cloud Close Date & Time

01 OCT 2021 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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="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"/>

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

Patient Cloud Close Date & Time

08 OCT 2021 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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="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"/>

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

Patient Cloud Close Date & Time

15 OCT 2021 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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"/>

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

Patient Cloud Close Date & Time

22 OCT 2021 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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"/>

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

Patient Cloud Close Date & Time

29 OCT 2021 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

Patient Cloud Close Date & Time

05 NOV 2021 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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="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"/>

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

Patient Cloud Close Date & Time

12 NOV 2021 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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"/>

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

Patient Cloud Close Date & Time

19 NOV 2021 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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"/>

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

Patient Cloud Close Date & Time

26 NOV 2021 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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"/>

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

Patient Cloud Close Date & Time

03 DEC 2021 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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"/>

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

Patient Cloud Close Date & Time

10 DEC 2021 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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="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"/>

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

Patient Cloud Close Date & Time

17 DEC 2021 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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°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"/>

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

Patient Cloud Close Date & Time

24 DEC 2021 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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="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"/>

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

Patient Cloud Close Date & Time

31 DEC 2021 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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"/>

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

Patient Cloud Close Date & Time

07 JAN 2022 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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"/>

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

Patient Cloud Close Date & Time

14 JAN 2022 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

Patient Cloud Close Date & Time

21 JAN 2022 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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="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"/>

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

Patient Cloud Close Date & Time

28 JAN 2022 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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"/>

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

Patient Cloud Close Date & Time

04 FEB 2022 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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"/>

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

Patient Cloud Close Date & Time

11 FEB 2022 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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°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"/>

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

Patient Cloud Close Date & Time

18 FEB 2022 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT	DAY 551
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

Patient Cloud Close Date & Time

25 FEB 2022 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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"/>

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

Patient Cloud Close Date & Time

04 MAR 2022 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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"/>

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

Patient Cloud Close Date & Time

11 MAR 2022 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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"/>

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

Patient Cloud Close Date & Time

18 MAR 2022 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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="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"/>

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

Patient Cloud Close Date & Time

25 MAR 2022 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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"/>

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

Patient Cloud Close Date & Time

01 APR 2022 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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="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"/>

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

Patient Cloud Close Date & Time

08 APR 2022 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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"/>

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

Patient Cloud Close Date & Time

15 APR 2022 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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"/>

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

Patient Cloud Close Date & Time

22 APR 2022 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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="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"/>

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

Patient Cloud Close Date & Time

29 APR 2022 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

Patient Cloud Close Date & Time

06 MAY 2022 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

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

Date and time of submission

Patient Cloud Open Date & Time

09 MAY 2022 00:01

Patient Cloud Close Date & Time

13 MAY 2022 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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"/>

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

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

Date and time of submission

Patient Cloud Open Date & Time

16 MAY 2022 00:01

Patient Cloud Close Date & Time

20 MAY 2022 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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="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"/>

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

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

Date and time of submission

Patient Cloud Open Date & Time

23 MAY 2022 00:01

Patient Cloud Close Date & Time

27 MAY 2022 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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="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"/>

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

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

Date and time of submission

Patient Cloud Open Date & Time

30 MAY 2022 00:01

Patient Cloud Close Date & Time

03 JUN 2022 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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"/>

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

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

Date and time of submission

Patient Cloud Open Date & Time

06 JUN 2022 00:01

Patient Cloud Close Date & Time

10 JUN 2022 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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="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"/>

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

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

Date and time of submission

Patient Cloud Open Date & Time

13 JUN 2022 00:01

Patient Cloud Close Date & Time

17 JUN 2022 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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"/>

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

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

Date and time of submission

Patient Cloud Open Date & Time

20 JUN 2022 00:01

Patient Cloud Close Date & Time

24 JUN 2022 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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"/>

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

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

Date and time of submission

Patient Cloud Open Date & Time

27 JUN 2022 00:01

Patient Cloud Close Date & Time

01 JUL 2022 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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="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"/>

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

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

Date and time of submission

Patient Cloud Open Date & Time

04 JUL 2022 00:01

Patient Cloud Close Date & Time

08 JUL 2022 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

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

Date and time of submission

Patient Cloud Open Date & Time

11 JUL 2022 00:01

Patient Cloud Close Date & Time

15 JUL 2022 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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°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"/>

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

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

Date and time of submission

Patient Cloud Open Date & Time

18 JUL 2022 00:01

Patient Cloud Close Date & Time

22 JUL 2022 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

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

Date and time of submission

Patient Cloud Open Date & Time

25 JUL 2022 00:01

Patient Cloud Close Date & Time

29 JUL 2022 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

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

Date and time of submission

Patient Cloud Open Date & Time

01 AUG 2022 00:01

Patient Cloud Close Date & Time

05 AUG 2022 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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="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"/>

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

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

Date and time of submission

Patient Cloud Open Date & Time

08 AUG 2022 00:01

Patient Cloud Close Date & Time

12 AUG 2022 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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"/>

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

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

Date and time of submission

Patient Cloud Open Date & Time

15 AUG 2022 00:01

Patient Cloud Close Date & Time

19 AUG 2022 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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°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"/>

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

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

Date and time of submission

Patient Cloud Open Date & Time

22 AUG 2022 00:01

Patient Cloud Close Date & Time

26 AUG 2022 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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"/>

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

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

Date and time of submission

Patient Cloud Open Date & Time

29 AUG 2022 00:01

Patient Cloud Close Date & Time

02 SEP 2022 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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="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"/>

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

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

Date and time of submission

Patient Cloud Open Date & Time

05 SEP 2022 00:01

Patient Cloud Close Date & Time

09 SEP 2022 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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"/>

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

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

Date and time of submission

Patient Cloud Open Date & Time

12 SEP 2022 00:01

Patient Cloud Close Date & Time

16 SEP 2022 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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="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"/>

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

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

Date and time of submission

Patient Cloud Open Date & Time

19 SEP 2022 00:01

Patient Cloud Close Date & Time

23 SEP 2022 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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"/>

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

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

Date and time of submission

Patient Cloud Open Date & Time

26 SEP 2022 00:01

Patient Cloud Close Date & Time

30 SEP 2022 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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°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"/>

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

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

Date and time of submission

Patient Cloud Open Date & Time

03 OCT 2022 00:01

Patient Cloud Close Date & Time

07 OCT 2022 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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"/>

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

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

Date and time of submission

Patient Cloud Open Date & Time

10 OCT 2022 00:01

Patient Cloud Close Date & Time

14 OCT 2022 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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="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"/>

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

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

Date and time of submission

Patient Cloud Open Date & Time

17 OCT 2022 00:01

Patient Cloud Close Date & Time

21 OCT 2022 23:59

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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°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"/>

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

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

Date and time of submission

Patient Cloud Open Date & Time

24 OCT 2022 00:01

Patient Cloud Close Date & Time

28 OCT 2022 23:59

US3272260

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:16:35

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		01 MAR 2021 18:45:22

US3272260

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 23:23:54

Generated On: 11 Aug 2021 22:16:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3272260

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 23:23:54

Generated On: 11 Aug 2021 22:16:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272260

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 23:23:53

Generated On: 11 Aug 2021 22:16:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3272260

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 23:23:53

Generated On: 11 Aug 2021 22:16:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272260

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 23:23:54

Generated On: 11 Aug 2021 22:16:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3272260

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 23:23:54

Generated On: 11 Aug 2021 22:16:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272260

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 23:23:54

Generated On: 11 Aug 2021 22:16:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3272260

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 23:23:54

Generated On: 11 Aug 2021 22:16:35

Is the participant continuing to the next visit?

Yes ☐

No ☒

Continuing Flag

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: COVID-19 Contact

Data signed: (b) (4) 29 Apr 2021 23:23:52

Generated On: 11 Aug 2021 22:16:35

Date of Contact	28 AUG 2020
Time of Contact	17:00
Date and Time of Contact (derived)	28 AUG 2020 17:00
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input type="checkbox"/></div> <div>Convalescent Tele-visit<input checked="" type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (1)

Data signed: (b) (4) 29 Apr 2021 23:23:52

Generated On: 11 Aug 2021 22:16:35

Symptom Day

Day 1	<input checked="" type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (1)

Data signed: (b) (4) 29 Apr 2021 23:23:52

Generated On: 11 Aug 2021 22:16:35

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	26 AUG 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	36.5 C	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (1)

Data signed: (b) (4) 29 Apr 2021 23:23:52

Generated On: 11 Aug 2021 22:16:35

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (1)

Data signed: (b) (4) 29 Apr 2021 23:23:52

Generated On: 11 Aug 2021 22:16:35

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (2)

Data signed: (b) (4) 29 Apr 2021 23:23:52

Generated On: 11 Aug 2021 22:16:35

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input checked="" type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (2)

Data signed: (b) (4) 29 Apr 2021 23:23:52

Generated On: 11 Aug 2021 22:16:35

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	29 AUG 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	99 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	98.4 F
-------------	--------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (2)

Data signed: (b) (4) 29 Apr 2021 23:23:52

Generated On: 11 Aug 2021 22:16:35

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (2)

Data signed: (b) (4) 29 Apr 2021 23:23:52

Generated On: 11 Aug 2021 22:16:35

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (3)

Data signed: (b) (4) 29 Apr 2021 23:23:52

Generated On: 11 Aug 2021 22:16:35

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input checked="" type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (3)

Data signed: (b) (4) 29 Apr 2021 23:23:52

Generated On: 11 Aug 2021 22:16:35

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	30 AUG 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (3)

Data signed: (b) (4) 29 Apr 2021 23:23:52

Generated On: 11 Aug 2021 22:16:35

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (3)

Data signed: (b) (4) 29 Apr 2021 23:23:52

Generated On: 11 Aug 2021 22:16:35

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (4)

Data signed: (b) (4) 29 Apr 2021 23:23:52

Generated On: 11 Aug 2021 22:16:35

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input checked="" type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (4)

Data signed: (b) (4) 29 Apr 2021 23:23:52

Generated On: 11 Aug 2021 22:16:35

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	31 AUG 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	99 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	98.1 F
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (4)

Data signed: (b) (4) 29 Apr 2021 23:23:52

Generated On: 11 Aug 2021 22:16:35

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (4)

Data signed: (b) (4) 29 Apr 2021 23:23:52

Generated On: 11 Aug 2021 22:16:35

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (5)

Data signed: (b) (4) 29 Apr 2021 23:23:52

Generated On: 11 Aug 2021 22:16:35

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input checked="" type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (5)

Data signed: (b) (4) 29 Apr 2021 23:23:52

Generated On: 11 Aug 2021 22:16:35

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	1 SEP 2020
------	------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	99 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	98.1 F
-------------	--------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (5)

Data signed: (b) (4) 29 Apr 2021 23:23:52

Generated On: 11 Aug 2021 22:16:35

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (5)

Data signed: (b) (4) 29 Apr 2021 23:23:52

Generated On: 11 Aug 2021 22:16:35

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (6)

Data signed: (b) (4) 29 Apr 2021 23:23:52

Generated On: 11 Aug 2021 22:16:35

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input checked="" type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (6)

Data signed: (b) (4) 29 Apr 2021 23:23:52

Generated On: 11 Aug 2021 22:16:35

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	2 SEP 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (6)

Data signed: (b) (4) 29 Apr 2021 23:23:52

Generated On: 11 Aug 2021 22:16:35

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (6)

Data signed: (b) (4) 29 Apr 2021 23:23:52

Generated On: 11 Aug 2021 22:16:35

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (7)

Data signed: (b) (4) 29 Apr 2021 23:23:52

Generated On: 11 Aug 2021 22:16:35

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input checked="" type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (7)

Data signed: (b) (4) 29 Apr 2021 23:23:52

Generated On: 11 Aug 2021 22:16:35

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	3 SEP 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	97.9 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (7)

Data signed: (b) (4) 29 Apr 2021 23:23:52

Generated On: 11 Aug 2021 22:16:35

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (7)

Data signed: (b) (4) 29 Apr 2021 23:23:52

Generated On: 11 Aug 2021 22:16:35

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (8)

Data signed: (b) (4) 29 Apr 2021 23:23:52

Generated On: 11 Aug 2021 22:16:35

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input checked="" type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (8)

Data signed: (b) (4) 29 Apr 2021 23:23:52

Generated On: 11 Aug 2021 22:16:35

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	27 AUG 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (8)

Data signed: (b) (4) 29 Apr 2021 23:23:52

Generated On: 11 Aug 2021 22:16:35

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (8)

Data signed: (b) (4) 29 Apr 2021 23:23:52

Generated On: 11 Aug 2021 22:16:35

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (9)

Data signed: (b) (4) 29 Apr 2021 23:23:52

Generated On: 11 Aug 2021 22:16:35

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input checked="" type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (9)

Data signed: (b) (4) 29 Apr 2021 23:23:52

Generated On: 11 Aug 2021 22:16:35

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	28 AUG 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (9)

Data signed: (b) (4) 29 Apr 2021 23:23:52

Generated On: 11 Aug 2021 22:16:35

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (9)

Data signed: (b) (4) 29 Apr 2021 23:23:52

Generated On: 11 Aug 2021 22:16:35

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 29 Apr 2021 23:23:52

Generated On: 11 Aug 2021 22:16:35

Date of Visit	28 AUG 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of Test	28 AUG 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	1

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 29 Apr 2021 23:23:52

Generated On: 11 Aug 2021 22:16:35

Did the subject have Respiratory Rates ≥ 30 per Minute? Yes ☐
No ☒

If Yes, provide:

Start Date _____

End Date _____

Respiratory Rate _____

Did the subject have Heart Rate ≥ 125 beats per minute? Yes ☐
No ☒

If Yes, provide:

Start Date _____

End Date _____

Heart Rate _____

Did the subject have Oxygen Saturation of SpO₂ $\leq 93\%$ on room air at sea level? Yes ☐
No ☒

If Yes, provide:

Start Date _____

End Date _____

Oxygen Saturation _____

Did the subject have PaO₂/FIO₂ Ratio < 300 mm Hg? Yes ☐
No ☒

If Yes, provide:

Start Date _____

End Date _____

PaO₂ _____

Did the subject have Respiratory failure? Yes ☐
No ☒

Start Date _____

Did the subject have Acute Respiratory Distress Syndrome (ARDS)? Yes ☐
No ☐

Start Date _____

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EAB) (1725)

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 29 Apr 2021 23:23:52

Generated On: 11 Aug 2021 22:16:35

If Yes to either Did subject require any of the following:

Ventilator Support:

High-Flow Oxygen? Yes ☐
No ☐

Start Date

End Date

Non-Invasive Ventilation? Yes ☐
No ☐

Start Date

End Date

Mechanical Ventilation? Yes ☐
No ☐

Start Date

End Date

ECMO? Yes ☐
No ☐

Start Date

End Date

Evidence of Shock:

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg Yes ☐
No ☒

Start Date

End Date

Evidence of Shock Requires Vasopressors Yes ☐
No ☒

Start Date

End Date

Acute Renal Dysfunction? Yes ☐
No ☒

Start Date

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 29 Apr 2021 23:23:52

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Hepatic Dysfunction? Yes ☐
No ☒

Start Date

Neurologic Dysfunction? Yes ☐
No ☒

Start Date

Evidence of Pneumonia:

Clinical Evidence Yes ☐
No ☒

Date of Assessment

Radiographical Evidence Yes ☐
No ☐

Date of Assessment

Admission to an intensive care unit due to SARS-CoV-2 Yes ☐
No ☒

Start Date

End Date

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 29 Apr 2021 23:23:52

Generated On: 11 Aug 2021 22:16:35

[Generate Next COVID-19 Assessment](#)

Yes ☒
No ☐

US3272260

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 29 Apr 2021 23:23:53

Generated On: 11 Aug 2021 22:16:35

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	31 AUG 2020
Day 5	Yes	1 SEP 2020
Day 7	No	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

US3272260

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 29 Apr 2021 23:23:53

Generated On: 11 Aug 2021 22:16:35

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3272260

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 29 Apr 2021 23:23:53

Generated On: 11 Aug 2021 22:16:35

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	28 AUG 2020
Time of assessment (00:00-23:59)	08:48 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 08:48
Height (xxx.x)	190.0 cm
Weight (xxx.x)	133.3 kg
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3272260

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Apr 2021 23:23:53

Generated On: 11 Aug 2021 22:16:35

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 AUG 2020

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

US3272260

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 29 Apr 2021 23:23:53

Generated On: 11 Aug 2021 22:16:35

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

28 AUG 2020

US3272260

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:16:35

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 _____

US3272260

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:35

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

US3272260

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:16:35

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.

US3272260

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:16:35

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☐

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

US3272260

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

Form: Visit Date

Data signed: (b) (4) 29 Apr 2021 23:23:53

Generated On: 11 Aug 2021 22:16:35

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

Visit date (dd MMM yyyy)	09 FEB 2021
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Was visit performed at the participant's home or at the clinic?	Home <input checked="" type="radio"/>
	Clinic <input type="radio"/>

Folder OID	UNBLND_DECIDE
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US3272260

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

Form: Unblinding

Data signed: (b) (4) 29 Apr 2021 23:23:53

Generated On: 11 Aug 2021 22:16:35

Date of updated informed consent (dd MMM yyyy)	09 FEB 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 checked="" type="radio"/> Amendment 6 or later <input type="radio"/>
Date of unblinding (dd MMM yyyy)	09 FEB 2021
Participant randomization assignment	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/>
Actual Dose 1	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input type="radio"/> Not Administered <input checked="" type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	
Continuing with mRNA-1273	1

US3272260

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 29 Apr 2021 23:23:53

Generated On: 11 Aug 2021 22:16:35

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

US3272260

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 29 Apr 2021 23:23:53

Generated On: 11 Aug 2021 22:16:35

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	25 FEB 2021
Time of assessment (00:00-23:59)	09:46 (24 HR)
Vital Signs Date and Time (derived)	25 FEB 2021 09:46
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3272260

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 29 Apr 2021 23:23:53

Generated On: 11 Aug 2021 22:16:35

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	25 FEB 2021
Time of assessment (00:00-23:59)	10:58 (24 HR)
Vital Signs Date and Time (derived)	25 FEB 2021 10:58
Temperature (xxx.x)	36.4 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3272260

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

Form: Physical Examination

Data signed: (b) (4) 29 Apr 2021 23:23:53

Generated On: 11 Aug 2021 22:16:35

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

25 FEB 2021

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

US3272260

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

Form: Exposure

Data signed: (b) (4) 29 Apr 2021 23:23:53

Generated On: 11 Aug 2021 22:16:35

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 25 FEB 2021

What was the treatment time? (00:00-23:59) 10:18 (24 HR)

Treatment Date and Time (derived) 25 FEB 2021 10:18

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

US3272260

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Apr 2021 23:23:53

Generated On: 11 Aug 2021 22:16:35

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

Collection date (dd MMM yyyy)	9 FEB 2021
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Collection time (00:00-23:59)	17:08 (24 HR)
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Collection date and time (derived)	9 FEB 2021 17:08
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US3272260

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 29 Apr 2021 23:23:53

Generated On: 11 Aug 2021 22:16:35

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

Collection date (dd MMM yyyy)	09 FEB 2021
-------------------------------	-------------

Collection time (00:00 - 23:59)	17:20
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Collection Date and Time (derived)	09 FEB 2021 17:20
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US3272260

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

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 23:23:53

Generated On: 11 Aug 2021 22:16:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272260

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 23:24:25

Generated On: 11 Aug 2021 22:16:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

04 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3272260

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 23:24:25

Generated On: 11 Aug 2021 22:16:35

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

US3272260

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 29 Apr 2021 23:23:53

Generated On: 11 Aug 2021 22:16:35

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3272260

Folder: OL-D29 (1)

Form: Vital Signs

Data signed: (b) (4) 29 Apr 2021 23:23:53

Generated On: 11 Aug 2021 22:16:35

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) _____

US3272260

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 29 Apr 2021 23:23:53

Generated On: 11 Aug 2021 22:16:35

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	17 MAR 2021
Time of assessment (00:00-23:59)	10:58 (24 HR)
Vital Signs Date and Time (derived)	17 MAR 2021 10:58
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3272260

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 29 Apr 2021 23:23:53

Generated On: 11 Aug 2021 22:16:35

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" 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	

US3272260

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Apr 2021 23:23:53

Generated On: 11 Aug 2021 22:16:35

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

17 MAR 2021

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

US3272260

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 29 Apr 2021 23:23:53

Generated On: 11 Aug 2021 22:16:35

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

SUBJECT RECEIVED 1 DOSE IN INITIAL ROUND OF VACCINATION.

What was the study treatment? _____

What was the treatment date? (dd MMM yyyy) _____

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

Treatment Date and Time (derived) _____

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

What was the frequency of the study treatment dosing? _____

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

US3272260

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Apr 2021 23:23:53

Generated On: 11 Aug 2021 22:16:35

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

Collection date (dd MMM yyyy)	17 MAR 2021
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Collection time (00:00-23:59)	11:00 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	17 MAR 2021 11:00
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US3272260

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 23:23:53

Generated On: 11 Aug 2021 22:16:35

Is the participant continuing to the next visit?

Yes ☐

No ☒

Continuing Flag

US3272260

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 14 Apr 2021 19:03:11

Generated On: 11 Aug 2021 22:16:35

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3272260

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 29 Apr 2021 23:23:52

Generated On: 11 Aug 2021 22:16:35

AEID

Adverse event

NASAL CONGESTION

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)

26 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)

29 AUG 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 29 Apr 2021 23:23:52

Generated On: 11 Aug 2021 22:16:35

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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input 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)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3272260

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 29 Apr 2021 23:23:52

Generated On: 11 Aug 2021 22:16:35

AEID	USA-US070-2020-MRNA-1273-P30 1000023
Adverse event	SYMPTOMATIC COVID 19
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	26 AUG 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)	29 AUG 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 29 Apr 2021 23:23:52

Generated On: 11 Aug 2021 22:16:35

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

US3272260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 14 Apr 2021 19:03:11

Generated On: 11 Aug 2021 22:16:35

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

Yes ☒

No ☐

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

US3272260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 14 Apr 2021 19:03:11

Generated On: 11 Aug 2021 22:16:35

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA PREVENTION

Dose per administration .5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3272260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 14 Apr 2021 19:03:11

Generated On: 11 Aug 2021 22:16:35

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		29 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)		29 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"/>

US3272260

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 14 Apr 2021 19:03:12

Generated On: 11 Aug 2021 22:16:35

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3272260

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 29 Apr 2021 23:23:52

Generated On: 11 Aug 2021 22:16:35

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

Primary reason for dosing discontinuation

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

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

US3272260

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 29 Apr 2021 23:23:52

Generated On: 11 Aug 2021 22:16:35

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 ☐

US3272260

Folder: SAE USA-US070-2020-MRNA-1273-P301000023

Form: Safety Report Form

Data signed: (b) (4) 29 Apr 2021 23:23:53

Generated On: 11 Aug 2021 22:16:35

SAEID	USA-US070-2020-MRNA-1273-P301000023
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	ADAM
Investigator's Last Name	BROSZ
Site Address: Street	2444 W. FAIDLEY AVE
Site Address: City	GRAND ISLAND
Site Address: State	NE
Site Address: Postal Code	68803
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3272260

Folder: SAE USA-US070-2020-MRNA-1273-P301000023

Form: Safety Report Form (1)

Data signed: (b) (4) 29 Apr 2021 23:23:53

Generated On: 11 Aug 2021 22:16:35

SAEID	USA-US070-2020-MRNA-1273-P301000023
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	ADAM
Investigator's Last Name	BROSZ
Site Address: Street	2444 W. FAIDLEY AVE
Site Address: City	GRAND ISLAND
Site Address: State	NE
Site Address: Postal Code	68803
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	20/NOV/2020 20:54
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

US3272260

Folder: SAE USA-US070-2020-MRNA-1273-P301000023

Form: Safety Report Form (2)

Data signed: (b) (4) 29 Apr 2021 23:23:53

Generated On: 11 Aug 2021 22:16:35

SAEID	USA-US070-2020-MRNA-1273-P301000023
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	ADAM
Investigator's Last Name	BROSZ
Site Address: Street	2444 W. FAIDLEY AVE
Site Address: City	GRAND ISLAND
Site Address: State	NE
Site Address: Postal Code	68803
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	03/DEC/2020 17:53
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

US3272260

Folder: SAE USA-US070-2020-MRNA-1273-P301000023

Form: Safety Report Form (3)

Data signed: (b) (4) 29 Apr 2021 23:23:53

Generated On: 11 Aug 2021 22:16:35

SAEID	USA-US070-2020-MRNA-1273-P301000023
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	ADAM
Investigator's Last Name	BROSZ
Site Address: Street	2444 W. FAIDLEY AVE
Site Address: City	GRAND ISLAND
Site Address: State	NE
Site Address: Postal Code	68803
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	11/DEC/2020 13:15
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

US3272260 (Prod: Meridian Clinical Research (Grand Island, Nebraska))

US3272260

Form: Participant Creation

Generated On: 11 Aug 2021 22:16:35

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'US3272260'	RWS_ENDPOINT ENDPOINT (b) (4)	22 Aug 2020 14:24:11

US3272260

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:16:35

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:25:23
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:05:35
User entered 'Yes (Y)'	Ashley Bell (b) (4)	22 Aug 2020 15:04:10

US3272260

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:25:23
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:05:35
User entered '22 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	22 Aug 2020 14:24:12

US3272260

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:25:23
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:05:35
User entered 'Clinic (Clinic)'	Ashley Bell (b) (4)	22 Aug 2020 15:04:10

US3272260

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:16:35

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:25:23
User entered 'SCRN'	System	22 Aug 2020 15:04:10

US3272260

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:16:35

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:25:23
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:05:42
User entered '(b) (6)1989'	RWS_ENDPOINT ENDPOINT (b) (4)	22 Aug 2020 14:24:13

US3272260

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:16:35

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:25:23
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:05:42
User entered '30'	Ashley Bell (b) (4)	22 Aug 2020 15:04:25

US3272260

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:16:35

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:25:23
User entered 'YEARS'	System	22 Aug 2020 15:04:25

US3272260

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:16:35

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:25:23
User entered '30'	System	22 Aug 2020 15:04:39

US3272260

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:16:35

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:25:23
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:05:42
User entered 'Male (M)' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Aug 2020 15:01:39
User entered 'Female (F)'	Ashley Bell (b) (4)	22 Aug 2020 15:04:25

US3272260

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:16:35

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:25:23
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:05:42
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Ashley Bell (b) (4)	22 Aug 2020 15:04:25

US3272260

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:16:35

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:25:23
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:05:42
User entered 'I'	Ashley Bell (b) (4)	22 Aug 2020 15:04:25

US3272260

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:16:35

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:25:23
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:05:42
User entered '0'	Ashley Bell (b) (4)	22 Aug 2020 15:04:25

US3272260

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:16:35

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:25:23
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:05:42
User entered '0'	Ashley Bell (b) (4)	22 Aug 2020 15:04:25

US3272260

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:16:35

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:25:23
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:05:42
User entered '0'	Ashley Bell (b) (4)	22 Aug 2020 15:04:25

US3272260

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:16:35

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:25:23
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:05:42
User entered '0'	Ashley Bell (b) (4)	22 Aug 2020 15:04:25

US3272260

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:16:35

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:25:23
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:05:42
User entered '0'	Ashley Bell (b) (4)	22 Aug 2020 15:04:25

US3272260

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:16:35

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:25:23
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:05:42
User entered empty.	Ashley Bell (b) (4)	22 Aug 2020 15:04:25

US3272260

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:16:35

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:25:23
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:05:42
User entered '0'	Ashley Bell (b) (4)	22 Aug 2020 15:04:25

US3272260

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:16:35

Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:25:23
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:05:42
User entered '0'	Ashley Bell (b) (4)	22 Aug 2020 15:04:25

US3272260

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:16:35

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:25:23
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:05:47
User entered '22 Aug 2020'	Ashley Bell (b) (4)	22 Aug 2020 15:04:39

US3272260

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:25:23
User entered 'Aug 2020'	System	22 Aug 2020 15:04:39

US3272260

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:25:23
User entered '2020'	System	22 Aug 2020 15:04:39

US3272260

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:16:35

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:25:23
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
Query 'Per CDM: Please confirm Protocol version, as Amendment 3 is dated 20Aug2020. Thank you' canceled (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 21:48:38
User opened query 'Per CDM: Please confirm Protocol version, as Amendment 3 is dated 20Aug2020. Thank you' (Site from DM).		06 Nov 2020 21:34:58
DataPoint Verified.		29 Sep 2020 17:05:47
User entered 'Amendment 2 (2)'	Ashley Bell (b) (4)	22 Aug 2020 15:04:39

US3272260

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:25:23
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:05:47
User entered 'Yes (Y)'	Ashley Bell (b) (4)	22 Aug 2020 15:04:39

US3272260

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:16:35

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:25:23
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:05:47
User entered empty.	Ashley Bell (b) (4)	22 Aug 2020 15:04:39

US3272260

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:16:35

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:25:23
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:05:47
User entered empty.	Ashley Bell (b) (4)	22 Aug 2020 15:04:39

US3272260

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:16:35

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:25:23
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:05:47
User entered 'No (N)'	Ashley Bell (b) (4)	22 Aug 2020 15:04:39

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Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:16:35

If Yes, [previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:25:23
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:05:47
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	22 Aug 2020 14:24:12

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Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:16:35

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:25:23
User entered '1'	System	22 Aug 2020 15:04:43

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:25:23
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:05:54
User entered 'Yes (Y)'	Ashley Bell (b) (4)	22 Aug 2020 15:04:43

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Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:16:35

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:25:23
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:06:04
User entered 'Yes (Y)'		26 Aug 2020 15:02:39

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Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:16:35

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:25:23
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 18:54:38
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' answered with 'PER PATIENT; HAS NOT NEEDED AN INHALER ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 23:59:56
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 13:07:17
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma exercise induced, LLT: Exercise induced asthma - version MedDRA\\23.0.	Coder Import (b) (4)	26 Aug 2020 15:04:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Aug 2020 15:04:47
Data point term sent to Coder	System	26 Aug 2020 15:03:48
User entered 'exercise induced asthma'	(b) (4), (b) (6)	26 Aug 2020 15:02:56

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Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:25:23
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 15:02:56

US3272260

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:16:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:25:23
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
User entered 'I'	(b) (4), (b) (6)	26 Aug 2020 15:02:56

US3272260

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:16:35

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:25:23
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 15:02:56

US3272260

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:25:23
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 15:02:56

US3272260

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:16:35

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:25:23
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
User entered '0'	(b) (4), (b) (6)	26 Aug 2020 15:02:56

US3272260

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:25:23
User entered empty.	System	26 Aug 2020 15:02:56

US3272260

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:25:23
User entered empty.	System	26 Aug 2020 15:02:56

US3272260

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:25:23
User entered empty.	System	26 Aug 2020 15:02:56

US3272260

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:25:23
User entered empty.	System	26 Aug 2020 15:02:56

US3272260

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:25:23
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
User closed query 'Per CDM: Patient noted as screened and dosed same day. Per CCGs pages 15-16, data to be entered for date, time, height and weight. Please update accordingly else clarify. ' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 09:27:10
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:06:21
Query 'Per CDM: Patient noted as screened and dosed same day. Per CCGs pages 15-16, data to be entered for date, time, height and weight. Please update accordingly else clarify. ' answered with 'UPDATED' (Site from DM).		25 Sep 2020 22:32:55
User entered 'Yes (Y)' reason for change: Data Entry Error		25 Sep 2020 22:32:51
User opened query 'Per CDM: Patient noted as screened and dosed same day. Per CCGs pages 15-16, data to be entered for date, time, height and weight. Please update accordingly else clarify. ' (Site from DM).		25 Sep 2020 14:07:30
User entered 'No (N)' reason for change: Data Entry Error		16 Sep 2020 18:39:47
User entered 'Yes (Y)'		26 Aug 2020 15:02:29

US3272260

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:25:23
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:06:21
User entered '22 Aug 2020' reason for change: Data Entry Error		25 Sep 2020 22:32:51
User entered empty; reason for change Data Entry Error		16 Sep 2020 18:39:47
User entered '22 Aug 2020'		26 Aug 2020 15:02:29

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Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:25:23
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:06:21
User entered '08:45' reason for change: Data Entry Error		25 Sep 2020 22:32:51
User entered empty; reason for change Data Entry Error		16 Sep 2020 18:39:47
User entered '08:45'		26 Aug 2020 15:02:29

US3272260

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:25:23
User entered '22 Aug 2020 08:45'	System	25 Sep 2020 22:32:51
User entered empty.	System	16 Sep 2020 18:39:47
User entered '22 Aug 2020 08:45'	System	26 Aug 2020 15:02:29

US3272260

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:25:23
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:06:21
User entered '188' cm reason for change: Data Entry Error		25 Sep 2020 22:32:51
User entered empty; reason for change Data Entry Error		16 Sep 2020 18:39:47
User entered '188' cm		26 Aug 2020 15:02:29
DataPoint set to visible.	System	22 Aug 2020 15:04:43

US3272260

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:35

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:25:23
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Un-verified.	(b) (4), (b) (6)	21 Nov 2020 14:25:38
User entered '134.1' kg reason for change: Data Entry Error		21 Nov 2020 14:25:38
DataPoint Verified.		29 Sep 2020 17:06:21
User entered '133.4' kg reason for change: Data Entry Error		25 Sep 2020 22:32:51
User entered empty; reason for change Data Entry Error		16 Sep 2020 18:39:47
User entered '134.4' kg		26 Aug 2020 15:02:29
DataPoint set to visible.	System	22 Aug 2020 15:04:43

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Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:35

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:25:23
User entered '37.94138'	System	21 Nov 2020 14:25:38
User entered '37.74332'	System	25 Sep 2020 22:32:51
User entered empty.	System	16 Sep 2020 18:39:47
User entered '38.0'	System	26 Aug 2020 15:02:29
DataPoint set to visible.	System	22 Aug 2020 15:04:43

US3272260

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:35

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:25:23
User entered 'kg/m2'	System	25 Sep 2020 22:32:51
User entered empty.	System	16 Sep 2020 18:39:47
User entered 'kg/m2'	System	26 Aug 2020 15:02:29
DataPoint set to visible.	System	22 Aug 2020 15:04:43

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Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:25:23
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
User closed query 'Per CDM Re-Query: Site response noted; however per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please enter "ND" as instructed. ' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 09:27:12
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:06:21
Query 'Per CDM Re-Query: Site response noted; however per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please enter "ND" as instructed. ' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 22:33:00
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	25 Sep 2020 22:32:51
User opened query 'Per CDM Re-Query: Site response noted; however per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please enter "ND" as instructed. ' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 14:07:35
User closed query 'Per CDM:Per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 14:07:35
Query 'Per CDM:Per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 18:39:52
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 18:39:47

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Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:35

Temperature (xxx.x)

Audit	User	Time (GMT)
User opened query 'Per CDM:Per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 08:15:31
User entered '36.6' C	(b) (4), (b) (6)	26 Aug 2020 15:02:29

US3272260

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:25:23
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:06:21
User entered empty; reason for change Data Entry Error		16 Sep 2020 18:39:47
User entered 'Oral (Oral)'		26 Aug 2020 15:02:29

US3272260

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:25:23
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:06:21
User entered empty.		26 Aug 2020 15:02:29

US3272260

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:25:23
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:06:21
User entered missing code ND - Not Done; reason for		25 Sep 2020 22:32:51
change Data Entry Error		
User entered empty; reason for change Data Entry		16 Sep 2020 18:39:47
Error		
User entered '98'		26 Aug 2020 15:02:29

US3272260

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:25:23
User entered 'bpm'	System	25 Sep 2020 22:32:51
User entered empty.	System	16 Sep 2020 18:39:47
User entered 'bpm'	System	26 Aug 2020 15:02:29

US3272260

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:25:23
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:06:21
User entered missing code ND - Not Done; reason for change Data Entry Error		25 Sep 2020 22:32:51
User entered empty; reason for change Data Entry Error		16 Sep 2020 18:39:47
User entered '15'		26 Aug 2020 15:02:29

US3272260

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:25:23
User entered 'breaths/min'	System	25 Sep 2020 22:32:51
User entered empty.	System	16 Sep 2020 18:39:47
User entered 'breaths/min'	System	26 Aug 2020 15:02:29

US3272260

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:25:23
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:06:21
User entered missing code ND - Not Done; reason for change Data Entry Error		25 Sep 2020 22:32:51
User entered empty; reason for change Data Entry Error		16 Sep 2020 18:39:47
User entered '138'		26 Aug 2020 15:02:29

US3272260

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:25:23
User entered 'mmHg'	System	25 Sep 2020 22:32:51
User entered empty.	System	16 Sep 2020 18:39:47
User entered 'mmHg'	System	26 Aug 2020 15:02:29

US3272260

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:35

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:25:23
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:06:21
User entered missing code ND - Not Done; reason for change Data Entry Error		25 Sep 2020 22:32:51
User entered empty; reason for change Data Entry Error		16 Sep 2020 18:39:47
User entered '81'		26 Aug 2020 15:02:29

US3272260

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:35

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:25:23
User entered 'mmHg'	System	25 Sep 2020 22:32:51
User entered empty.	System	16 Sep 2020 18:39:47
User entered 'mmHg'	System	26 Aug 2020 15:02:29

US3272260

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:35

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:25:23

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Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:35

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:25:23

US3272260

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:16:35

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:25:23
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:06:26
User entered 'Yes (Y)'		26 Aug 2020 15:01:50

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Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:16:35

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:25:23
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:06:26
User entered '22 Aug 2020'		26 Aug 2020 15:01:50

US3272260

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:25:23
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:06:36
User entered 'Yes (Y)'		26 Aug 2020 15:01:07

US3272260

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:25:23
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:06:36
User entered 'No (N)'		26 Aug 2020 15:01:07

US3272260

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:25:23
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:06:36
User entered 'No (N)'		26 Aug 2020 15:01:07

US3272260

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:25:23
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:06:36
User entered 'No (N)'		26 Aug 2020 15:01:07

US3272260

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:25:23
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:06:36
User entered 'No (N)'		26 Aug 2020 15:01:07

US3272260

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:25:23
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:06:36
User entered 'No (N)'		26 Aug 2020 15:01:07

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:25:23
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:06:36
User entered 'No (N)'		26 Aug 2020 15:01:07

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:25:23
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:06:36
User entered 'No (N)'		26 Aug 2020 15:01:07

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:25:23
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:06:36
User entered 'No (N)'		26 Aug 2020 15:01:07

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:25:23
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:06:36
User entered 'No (N)'		26 Aug 2020 15:01:07

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:25:23
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:06:36
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 15:01:07

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:16:35

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:25:23
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:06:36
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 15:01:07

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Folder: Screening

Form: Risk of Exposure

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:25:23
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:06:36
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 15:01:07

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Folder: Screening

Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:25:23
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
User entered '0'	(b) (4), (b) (6)	26 Aug 2020 15:01:07

US3272260

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:16:35

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:25:23
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:06:36
User entered '0'	(b) (4), (b) (6)	26 Aug 2020 15:01:07

US3272260

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:25:23
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:06:36
User entered '0'	(b) (4), (b) (6)	26 Aug 2020 15:01:07

US3272260

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:25:23
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:06:36
User entered '0'	(b) (4), (b) (6)	26 Aug 2020 15:01:07

US3272260

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:25:23
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:06:36
User entered '0'	(b) (4), (b) (6)	26 Aug 2020 15:01:07

US3272260

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:25:23
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:06:36
User entered 'I'	(b) (4), (b) (6)	26 Aug 2020 15:01:07

US3272260

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:16:35

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:25:23
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
User entered '0'	(b) (4), (b) (6)	26 Aug 2020 15:01:07

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:16:35

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:25:23
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:06:36
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 15:01:07

US3272260

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:16:35

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:54:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:06:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 15:03:09

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:54:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:06:52
User entered '22 Aug 2020'	(b) (4), (b) (6)	26 Aug 2020 15:03:09

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:54:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:06:52
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	26 Aug 2020 15:03:09

US3272260

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:16:35

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:54:53
User entered 'VISIT1'	System	26 Aug 2020 15:03:09

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:54:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:06:56
User entered '22 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	22 Aug 2020 14:29:10

US3272260

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:54:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:06:56
User entered '107401'	RWS_ENDPOINT ENDPOINT (b) (4)	22 Aug 2020 14:29:10

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:54:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:06:56
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	22 Aug 2020 14:29:10

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:16:35

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)	02 May 2021 12:54:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:06:56
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 15:03:15

US3272260

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:16:35

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)	02 May 2021 12:54:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:06:56
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 15:03:15

US3272260

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:54:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:06:56
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 15:03:15

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:54:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:06:56
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 15:03:15

US3272260

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:16:35

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:54:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:06:56
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 15:03:15

US3272260

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:16:35

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:54:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
User closed query 'Please verify as HIV is not in medical history nor is an HIV medication listed on Con Med log' (Site from CRA).	(b) (4), (b) (6)	29 Dec 2020 02:28:28
Query 'Please verify as HIV is not in medical history nor is an HIV medication listed on Con Med log' answered with 'updated' (Site from CRA).		18 Dec 2020 21:31:19
User entered 'No (N)' reason for change: Data Entry Error		18 Dec 2020 21:31:04
User opened query 'Please verify as HIV is not in medical history nor is an HIV medication listed on Con Med log' (Site from CRA).		17 Dec 2020 00:51:54
User entered 'Yes (Y)'		08 Nov 2020 15:45:10
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:39:09
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 02:18:09

US3272260

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:16:35

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:54:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
User closed query 'Per CDM: Kindly remove the cm.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 09:12:25
Query 'Per CDM: Kindly remove the cm.' answered with 'updated' (Site from DM).	Kayla Flege (b) (4)	19 Nov 2020 22:55:56
User entered missing code ND - Not Done; reason for change Data Entry Error	Kayla Flege (b) (4)	19 Nov 2020 22:55:51
User opened query 'Per CDM: Kindly remove the cm.' (Site from DM).	(b) (4), (b) (6)	07 Nov 2020 17:59:52
User closed query 'Per CDM: If a participant is screened, enrolled, randomized, and dosed on the same day then 'Height/Weight' should be recorded as "Not done" at this visit (V1D1). Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 20:36:00
Query 'Per CDM: If a participant is screened, enrolled, randomized, and dosed on the same day then 'Height/Weight' should be recorded as "Not done" at this visit (V1D1). Please review and update accordingly.' answered with 'updated' (Site from DM).	Ashley Bell (b) (4)	07 Oct 2020 19:14:30
DataPoint Un-verified.	Ashley Bell (b) (4)	07 Oct 2020 19:14:25
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	07 Oct 2020 19:14:25
User opened query 'Per CDM: If a participant is screened, enrolled, randomized, and dosed on the same day then 'Height/Weight' should be recorded as "Not done" at this visit (V1D1). Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 22:06:17
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:07:19
User entered '188' cm	(b) (4), (b) (6)	26 Aug 2020 15:04:29

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:16:35

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:54:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
User closed query 'Per CDM; Kindly remove the kg.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 09:12:35
Query 'Per CDM; Kindly remove the kg.' answered with 'updated' (Site from DM).	Kayla Flege (b) (4)	19 Nov 2020 22:56:01
User entered missing code ND - Not Done; reason for change Data Entry Error	Kayla Flege (b) (4)	19 Nov 2020 22:55:51
User opened query 'Per CDM; Kindly remove the kg.' (Site from DM).	(b) (4), (b) (6)	07 Nov 2020 18:00:23
DataPoint Un-verified.	Ashley Bell (b) (4)	07 Oct 2020 19:14:25
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	07 Oct 2020 19:14:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:07:19
User entered '134.1' kg		26 Aug 2020 15:04:29

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:16:35

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:54:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
User closed query 'Per CDM: Kindly remove the cm.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 09:12:25
Query 'Per CDM: Kindly remove the cm.' answered with 'updated' (Site from DM).	Kayla Flege (b) (4)	19 Nov 2020 22:55:56
User entered missing code ND - Not Done; reason for change Data Entry Error	Kayla Flege (b) (4)	19 Nov 2020 22:55:51
User opened query 'Per CDM: Kindly remove the cm.' (Site from DM).	(b) (4), (b) (6)	07 Nov 2020 17:59:52
User closed query 'Per CDM: If a participant is screened, enrolled, randomized, and dosed on the same day then 'Height/Weight' should be recorded as "Not done" at this visit (V1D1). Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 20:36:00
Query 'Per CDM: If a participant is screened, enrolled, randomized, and dosed on the same day then 'Height/Weight' should be recorded as "Not done" at this visit (V1D1). Please review and update accordingly.' answered with 'updated' (Site from DM).	Ashley Bell (b) (4)	07 Oct 2020 19:14:30
DataPoint Un-verified.	Ashley Bell (b) (4)	07 Oct 2020 19:14:25
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	07 Oct 2020 19:14:25
User opened query 'Per CDM: If a participant is screened, enrolled, randomized, and dosed on the same day then 'Height/Weight' should be recorded as "Not done" at this visit (V1D1). Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 22:06:17
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:07:19
User entered '188' cm	(b) (4), (b) (6)	26 Aug 2020 15:04:29

US3272260

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:16:35

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:54:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
User closed query 'Per CDM; Kindly remove the kg.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 09:12:35
Query 'Per CDM; Kindly remove the kg.' answered with 'updated' (Site from DM).	Kayla Flege (b) (4)	19 Nov 2020 22:56:01
User entered missing code ND - Not Done; reason for change Data Entry Error	Kayla Flege (b) (4)	19 Nov 2020 22:55:51
User opened query 'Per CDM; Kindly remove the kg.' (Site from DM).	(b) (4), (b) (6)	07 Nov 2020 18:00:23
DataPoint Un-verified.	Ashley Bell (b) (4)	07 Oct 2020 19:14:25
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	07 Oct 2020 19:14:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:07:19
User entered '134.1' kg		26 Aug 2020 15:04:29

US3272260

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:35

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:54:53
User accepted default value 'Pre-Dose (PREDOSE)'		26 Aug 2020 15:04:29

US3272260

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:54:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:07:19
User entered 'Yes (Y)'		26 Aug 2020 15:04:29

US3272260

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:54:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:07:19
User entered '22 Aug 2020'		26 Aug 2020 15:04:29

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:54:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:07:19
User entered '08:45'		26 Aug 2020 15:04:29

US3272260

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:54:53
User entered '22 Aug 2020 08:45'	System	26 Aug 2020 15:04:29

US3272260

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:54:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:07:19
User entered '36.6' C		26 Aug 2020 15:04:29

US3272260

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:54:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:07:19
User entered 'Oral (Oral)'		26 Aug 2020 15:04:29

US3272260

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:54:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:07:19
User entered empty.		26 Aug 2020 15:04:29

US3272260

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:54:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:07:19
User entered '98'		26 Aug 2020 15:04:29

US3272260

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:54:53
User entered 'bpm'	System	26 Aug 2020 15:04:29

US3272260

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:54:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:07:19
User entered '15'		26 Aug 2020 15:04:29

US3272260

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:54:53
User entered 'breaths/min'	System	26 Aug 2020 15:04:29

US3272260

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:35

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:54:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:07:19
User entered '138'		26 Aug 2020 15:04:29

US3272260

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:54:53
User entered 'mmHg'	System	26 Aug 2020 15:04:29

US3272260

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:35

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:54:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:07:19
User entered '81'		26 Aug 2020 15:04:29

US3272260

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:35

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:54:53
User entered 'mmHg'	System	26 Aug 2020 15:04:29

US3272260

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:16:35

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:54:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
User closed query 'Per CDM: Kindly remove the cm.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 09:12:25
Query 'Per CDM: Kindly remove the cm.' answered with 'updated' (Site from DM).	Kayla Flege (b) (4)	19 Nov 2020 22:55:56
User entered missing code ND - Not Done; reason for change Data Entry Error	Kayla Flege (b) (4)	19 Nov 2020 22:55:51
User opened query 'Per CDM: Kindly remove the cm.' (Site from DM).	(b) (4)	07 Nov 2020 17:59:52
User closed query 'Per CDM: If a participant is screened, enrolled, randomized, and dosed on the same day then 'Height/Weight' should be recorded as "Not done" at this visit (V1D1). Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 20:36:00
Query 'Per CDM: If a participant is screened, enrolled, randomized, and dosed on the same day then 'Height/Weight' should be recorded as "Not done" at this visit (V1D1). Please review and update accordingly.' answered with 'updated' (Site from DM).	Ashley Bell (b) (4)	07 Oct 2020 19:14:30
DataPoint Un-verified.	Ashley Bell (b) (4)	07 Oct 2020 19:14:25
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	07 Oct 2020 19:14:25
User opened query 'Per CDM: If a participant is screened, enrolled, randomized, and dosed on the same day then 'Height/Weight' should be recorded as "Not done" at this visit (V1D1). Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 22:06:17
DataPoint Verified.		29 Sep 2020 17:07:19
User entered '188' cm		26 Aug 2020 15:04:29

US3272260

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:16:35

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:54:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
User closed query 'Per CDM; Kindly remove the kg.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 09:12:35
Query 'Per CDM; Kindly remove the kg.' answered with 'updated' (Site from DM).	Kayla Flege (b) (4)	19 Nov 2020 22:56:01
User entered missing code ND - Not Done; reason for change Data Entry Error	Kayla Flege (b) (4)	19 Nov 2020 22:55:51
User opened query 'Per CDM; Kindly remove the kg.' (Site from DM).	(b) (4), (b) (6)	07 Nov 2020 18:00:23
DataPoint Un-verified.	Ashley Bell (b) (4)	07 Oct 2020 19:14:25
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	07 Oct 2020 19:14:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:07:19
User entered '134.1' kg		26 Aug 2020 15:04:29

US3272260

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:35

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:54:53
User accepted default value 'Post-Dose (POSTDOSE)'		26 Aug 2020 15:04:29

US3272260

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:54:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:07:19
User entered 'Yes (Y)'		26 Aug 2020 15:04:29

US3272260

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:54:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:07:19
User entered '22 Aug 2020'		26 Aug 2020 15:04:29

US3272260

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:54:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:07:19
User entered '10:28'		26 Aug 2020 15:04:29

US3272260

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:54:53
User entered '22 Aug 2020 10:28'	System	26 Aug 2020 15:04:29

US3272260

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:54:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:07:19
User entered '36.5' C		26 Aug 2020 15:04:29

US3272260

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:54:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:07:19
User entered 'Oral (Oral)'		26 Aug 2020 15:04:29

US3272260

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:54:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:07:19
User entered empty.		26 Aug 2020 15:04:29

US3272260

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:54:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:07:19
User entered '76'		26 Aug 2020 15:04:29

US3272260

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:54:53
User entered 'bpm'	System	26 Aug 2020 15:04:29

US3272260

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:54:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:07:19
User entered '24'		26 Aug 2020 15:04:29

US3272260

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:54:53
User entered 'breaths/min'	System	26 Aug 2020 15:04:29

US3272260

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:35

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:54:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:07:19
User entered '128'		26 Aug 2020 15:04:29

US3272260

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:54:53
User entered 'mmHg'	System	26 Aug 2020 15:04:29

US3272260

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:35

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:54:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:07:19
User entered '86'		26 Aug 2020 15:04:29

US3272260

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:35

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:54:53
User entered 'mmHg'	System	26 Aug 2020 15:04:29

US3272260

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:16:35

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:54:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:07:25
User entered 'Yes (Y)'		26 Aug 2020 15:04:36

US3272260

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:16:35

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:54:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:07:25
User entered '22 Aug 2020'		26 Aug 2020 15:04:36

US3272260

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:16:35

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:54:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:07:43
User entered 'Yes (Y)'	Ashley Bell (b) (4)	22 Aug 2020 15:05:04

US3272260

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:16:35

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:54:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:07:43
User entered empty.	Ashley Bell (b) (4)	22 Aug 2020 15:05:04

US3272260

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:16:35

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)	02 May 2021 12:54:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:07:43
User entered empty.	Ashley Bell (b) (4)	22 Aug 2020 15:05:04

US3272260

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:16:35

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:54:53
User entered 'MRNA-1273 OR PLACEBO'	System	22 Aug 2020 15:05:04

US3272260

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:16:35

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:54:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:07:43
User entered '22 Aug 2020'	Ashley Bell (b) (4)	22 Aug 2020 15:05:04

US3272260

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:54:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:07:43
User entered '09:57'	Ashley Bell (b) (4)	22 Aug 2020 15:05:04

US3272260

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:54:53
User entered '22 Aug 2020 09:57'	System	22 Aug 2020 15:05:04

US3272260

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:54:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:07:43
User entered 'Left Arm (LEFT ARM)'	Ashley Bell (b) (4)	22 Aug 2020 15:05:04

US3272260

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:54:53
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:07:43
User entered 'ONCE'	System	22 Aug 2020 15:05:04

US3272260

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:16:35

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:54:53
User entered 'INTRAMUSCULAR'	System	22 Aug 2020 15:05:04

US3272260

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:16:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:54:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:07:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 15:05:04

US3272260

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:16:35

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:54:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:07:50
User entered '22 Aug 2020'	(b) (4), (b) (6)	26 Aug 2020 15:05:04

US3272260

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:54:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:07:50
User entered '09:20'	(b) (4), (b) (6)	26 Aug 2020 15:05:04

US3272260

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:54:53
User entered '22 Aug 2020 09:20'	System	26 Aug 2020 15:05:04

US3272260

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:16:35

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:54:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:08:01
User entered '22 Aug 2020'	(b) (4), (b) (6)	26 Aug 2020 15:05:14

US3272260

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:16:35

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:54:53
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'		26 Aug 2020 15:05:14

US3272260

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:16:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:54:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:08:01
User entered 'Yes (Y)'		26 Aug 2020 15:05:14

US3272260

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:16:35

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:54:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:08:01
User entered '09:13'		26 Aug 2020 15:05:14

US3272260

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:54:53
User entered '22 Aug 2020 09:13'	System	26 Aug 2020 15:05:14

US3272260

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:16:35

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:54:53
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'		26 Aug 2020 15:05:14

US3272260

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:16:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:54:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:08:01
User entered 'No (N)'		26 Aug 2020 15:05:14

US3272260

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:16:35

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:54:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:08:01
User entered empty.		26 Aug 2020 15:05:14

US3272260

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:54:53
User entered empty.	System	26 Aug 2020 15:05:14

US3272260

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:54:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:08:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 15:05:18

US3272260

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:16:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:54:53
User entered 'I'	System	26 Aug 2020 15:05:18

US3272260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
Data entry locked.	System	22 Aug 2020 15:05:04
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Aug 2020 15:05:04

US3272260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:16:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-22T10:26:59', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: 'afbd756b-ae4e-44b9-94db-a00a29844eda' User entered 'Yes (Y)'	System	22 Aug 2020 15:27:24
	System	22 Aug 2020 15:27:24

US3272260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:16:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-22T10:27:10', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: 'afbd756b-aeef-44b9-94db-a00a29844eda' User entered '97.8'	System	22 Aug 2020 15:27:24
	System	22 Aug 2020 15:27:24

US3272260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-22T10:27:18', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: 'afbd756b-ae4e-44b9-94db-a00a29844eda'	System	22 Aug 2020 15:27:24
User entered 'No (N)'	System	22 Aug 2020 15:27:24

US3272260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-22T10:27:21', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: 'afbd756b-ae4e-44b9-94db-a00a29844eda' User entered '22 Aug 2020 10:27'	System	22 Aug 2020 15:27:24
	System	22 Aug 2020 15:27:24

US3272260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
User entered '22 Aug 2020 10:17'	System	22 Aug 2020 15:05:04

US3272260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
User entered '22 Aug 2020 12:47'	System	22 Aug 2020 15:05:04

US3272260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
Data entry locked.	System	22 Aug 2020 15:05:04
User entered 'Day 1, after vaccination (at home)'	System	22 Aug 2020 15:05:04

US3272260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:16:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-22T23:23:18', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '54eceb1a-fda8-4291-ba4d-f8361c895ab5' User entered 'Yes (Y)'	System	23 Aug 2020 04:23:39
	System	23 Aug 2020 04:23:39

US3272260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:16:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-22T23:23:26', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '54eceb1a-fda8-4291-ba4d-f8361c895ab5' User entered '98.1'	System	23 Aug 2020 04:23:39
	System	23 Aug 2020 04:23:39

US3272260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-22T23:23:31', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '54eceb1a-fda8-4291-ba4d-f8361c895ab5'	System	23 Aug 2020 04:23:39
User entered 'No (N)'	System	23 Aug 2020 04:23:39

US3272260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-22T23:23:34', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '54eceb1a-fda8-4291-ba4d-f8361c895ab5' User entered '22 Aug 2020 23:23'	System	23 Aug 2020 04:23:39
	System	23 Aug 2020 04:23:39

US3272260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
User entered '22 Aug 2020 13:42'	System	22 Aug 2020 15:05:04

US3272260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
User entered '23 Aug 2020 11:59'	System	22 Aug 2020 15:05:04

US3272260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
Data entry locked.	System	22 Aug 2020 15:05:04
User entered 'Day 2'	System	22 Aug 2020 15:05:04

US3272260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:16:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-23T22:53:43', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '3adb20cd-786c-42d8-b713-61d3616fb3f9' User entered 'Yes (Y)'	System	24 Aug 2020 03:53:59
	System	24 Aug 2020 03:53:59

US3272260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:16:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-23T22:53:49', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '3adb20cd-786c-42d8-b713-61d3616fb3f9' User entered '97.7'	System	24 Aug 2020 03:53:59
	System	24 Aug 2020 03:53:59

US3272260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-23T22:53:55', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '3adb20cd-786c-42d8-b713-61d3616fb3f9'	System	24 Aug 2020 03:53:59
User entered 'No (N)'	System	24 Aug 2020 03:53:59

US3272260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-23T22:53:58', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '3adb20cd-786c-42d8-b713-61d3616fb3f9' User entered '23 Aug 2020 22:53'	System	24 Aug 2020 03:53:59
	System	24 Aug 2020 03:53:59

US3272260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
User entered '23 Aug 2020 12:00'	System	22 Aug 2020 15:05:04

US3272260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
User entered '24 Aug 2020 11:59'	System	22 Aug 2020 15:05:04

US3272260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
Data entry locked.	System	22 Aug 2020 15:05:04
User entered 'Day 3'	System	22 Aug 2020 15:05:04

US3272260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:16:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-24T22:26:35', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: 'f94d7283-b091-4806-9f56-370435d9cbf2'	System	25 Aug 2020 03:26:51
User entered 'Yes (Y)'	System	25 Aug 2020 03:26:51

US3272260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:16:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-24T22:26:41', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: 'f94d7283-b091-4806-9f56-370435d9cbf2'	System	25 Aug 2020 03:26:51
User entered '97.8'	System	25 Aug 2020 03:26:51

US3272260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-24T22:26:47', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: 'f94d7283-b091-4806-9f56-370435d9cbf2'	System	25 Aug 2020 03:26:51
User entered 'No (N)'	System	25 Aug 2020 03:26:51

US3272260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-24T22:26:49', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: 'f94d7283-b091-4806-9f56-370435d9cbf2'	System	25 Aug 2020 03:26:51
User entered '24 Aug 2020 22:26'	System	25 Aug 2020 03:26:51

US3272260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
User entered '24 Aug 2020 12:00'	System	22 Aug 2020 15:05:04

US3272260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
User entered '25 Aug 2020 11:59'	System	22 Aug 2020 15:05:04

US3272260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
Data entry locked.	System	22 Aug 2020 15:05:04
User entered 'Day 4'	System	22 Aug 2020 15:05:04

US3272260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:16:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-25T21:21:20', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '88bd4f1e-8bc0-4029-a84e-6c75a0eeaffd' User entered 'Yes (Y)'	System	26 Aug 2020 02:21:50
	System	26 Aug 2020 02:21:50

US3272260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:16:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-25T21:21:30', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '88bd4f1e-8bc0-4029-a84e-6c75a0eeaffd' User entered '98.0'	System	26 Aug 2020 02:21:50
	System	26 Aug 2020 02:21:50

US3272260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-25T21:21:42', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '88bd4f1e-8bc0-4029-a84e-6c75a0eeaffd'	System	26 Aug 2020 02:21:50
User entered 'No (N)'	System	26 Aug 2020 02:21:50

US3272260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-25T21:21:45', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '88bd4f1e-8bc0-4029-a84e-6c75a0eeaffd' User entered '25 Aug 2020 21:21'	System	26 Aug 2020 02:21:50
	System	26 Aug 2020 02:21:50

US3272260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
User entered '25 Aug 2020 12:00'	System	22 Aug 2020 15:05:04

US3272260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
User entered '26 Aug 2020 11:59'	System	22 Aug 2020 15:05:04

US3272260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
Data entry locked.	System	22 Aug 2020 15:05:04
User entered 'Day 5'	System	22 Aug 2020 15:05:04

US3272260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:16:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-26T22:11:24', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '8f0a742a-190f-47fc-abc0-edfd8462d8d9' User entered 'Yes (Y)'	System	27 Aug 2020 03:11:58
	System	27 Aug 2020 03:11:58

US3272260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:16:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-26T22:11:29', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '8f0a742a-190f-47fc-abc0-edfd8462d8d9' User entered '97.8'	System	27 Aug 2020 03:11:58
	System	27 Aug 2020 03:11:58

US3272260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-26T22:11:51', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '8f0a742a-190f-47fc-abc0-edfd8462d8d9'	System	27 Aug 2020 03:11:58
User entered 'No (N)'	System	27 Aug 2020 03:11:58

US3272260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-26T22:11:53', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '8f0a742a-190f-47fc-abc0-edfd8462d8d9' User entered '26 Aug 2020 22:11'	System	27 Aug 2020 03:11:58
	System	27 Aug 2020 03:11:58

US3272260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
User entered '26 Aug 2020 12:00'	System	22 Aug 2020 15:05:04

US3272260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
User entered '27 Aug 2020 11:59'	System	22 Aug 2020 15:05:04

US3272260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
Data entry locked.	System	22 Aug 2020 15:05:04
User entered 'Day 6'	System	22 Aug 2020 15:05:04

US3272260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:16:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-27T21:36:47', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '94bfe2fc-38bb-46b1-acea-3e80353ba81b' User entered 'Yes (Y)'	System	28 Aug 2020 02:37:05
	System	28 Aug 2020 02:37:05

US3272260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:16:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-27T21:36:52', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '94bfe2fc-38bb-46b1-acea-3e80353ba81b' User entered '97.8'	System	28 Aug 2020 02:37:05
	System	28 Aug 2020 02:37:05

US3272260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-27T21:36:56', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '94bfe2fc-38bb-46b1-acea-3e80353ba81b'	System	28 Aug 2020 02:37:05
User entered 'No (N)'	System	28 Aug 2020 02:37:05

US3272260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-27T21:36:58', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '94bfe2fc-38bb-46b1-acea-3e80353ba81b' User entered '27 Aug 2020 21:36'	System	28 Aug 2020 02:37:05
	System	28 Aug 2020 02:37:05

US3272260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
User entered '27 Aug 2020 12:00'	System	22 Aug 2020 15:05:04

US3272260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
User entered '28 Aug 2020 11:59'	System	22 Aug 2020 15:05:04

US3272260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
Data entry locked.	System	22 Aug 2020 15:05:04
User entered 'Day 7'	System	22 Aug 2020 15:05:04

US3272260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:16:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-28T21:09:59', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '20d9269f-0832-4c0b-993e-a03d9df9c375'	System	29 Aug 2020 02:10:13
User entered 'Yes (Y)'	System	29 Aug 2020 02:10:13

US3272260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:16:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-28T21:10:04', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '20d9269f-0832-4c0b-993e-a03d9df9c375' User entered '97.7'	System	29 Aug 2020 02:10:13
	System	29 Aug 2020 02:10:13

US3272260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-28T21:10:06', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '20d9269f-0832-4c0b-993e-a03d9df9c375'	System	29 Aug 2020 02:10:13
User entered 'No (N)'	System	29 Aug 2020 02:10:13

US3272260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-28T21:10:09', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '20d9269f-0832-4c0b-993e-a03d9df9c375'	System	29 Aug 2020 02:10:13
User entered '28 Aug 2020 21:10'	System	29 Aug 2020 02:10:13

US3272260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
User entered '28 Aug 2020 12:00'	System	22 Aug 2020 15:05:04

US3272260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
User entered '29 Aug 2020 11:59'	System	22 Aug 2020 15:05:04

US3272260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
Data entry locked.	System	22 Aug 2020 15:05:04
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Aug 2020 15:05:04

US3272260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:16:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-22T10:19:35', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: 'aaabd3cd-dfc9-42fd-8f4c-ed983b3fe892'	System	22 Aug 2020 15:20:07
User entered 'Does not interfere with activity (2)'	System	22 Aug 2020 15:20:07

US3272260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:16:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-22T10:19:50', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: 'aaabd3cd-dfc9-42fd-8f4c-ed983b3fe892'	System	22 Aug 2020 15:20:07
User entered 'No (N)'	System	22 Aug 2020 15:20:07

US3272260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-22T10:19:56', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: 'aaabd3cd-dfc9-42fd-8f4c-ed983b3fe892'	System	22 Aug 2020 15:20:07
User entered 'No (N)'	System	22 Aug 2020 15:20:07

US3272260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:16:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-22T10:20:00', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: 'aaabd3cd-dfc9-42fd-8f4c-ed983b3fe892'	System	22 Aug 2020 15:20:07
User entered 'None (1)'	System	22 Aug 2020 15:20:07

US3272260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-22T10:20:02', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: 'aaabd3cd-dfc9-42fd-8f4c-ed983b3fe892'	System	22 Aug 2020 15:20:07
User entered '22 Aug 2020 10:20'	System	22 Aug 2020 15:20:07

US3272260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
User entered '22 Aug 2020 10:17'	System	22 Aug 2020 15:05:04

US3272260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
User entered '22 Aug 2020 12:47'	System	22 Aug 2020 15:05:04

US3272260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
Data entry locked.	System	22 Aug 2020 15:05:04
User entered 'Day 1, after vaccination (at home)'	System	22 Aug 2020 15:05:04

US3272260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:16:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-22T23:23:43', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: 'b1ea4d22-f766-4655-8315-0b3ae2187ab0'	System	23 Aug 2020 04:24:06
User entered 'Does not interfere with activity (2)'	System	23 Aug 2020 04:24:06

US3272260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:16:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-22T23:23:46', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: 'b1ea4d22-f766-4655-8315-0b3ae2187ab0' User entered 'No (N)'	System	23 Aug 2020 04:24:06
	System	23 Aug 2020 04:24:06

US3272260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-22T23:23:50', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: 'b1ea4d22-f766-4655-8315-0b3ae2187ab0' User entered 'No (N)'	System	23 Aug 2020 04:24:06
	System	23 Aug 2020 04:24:06

US3272260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:16:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-22T23:23:59', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: 'b1ea4d22-f766-4655-8315-0b3ae2187ab0' User entered 'None (1)'	System	23 Aug 2020 04:24:06
	System	23 Aug 2020 04:24:06

US3272260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-22T23:24:03', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: 'b1ea4d22-f766-4655-8315-0b3ae2187ab0' User entered '22 Aug 2020 23:24'	System	23 Aug 2020 04:24:06
	System	23 Aug 2020 04:24:06

US3272260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
User entered '22 Aug 2020 13:42'	System	22 Aug 2020 15:05:04

US3272260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
User entered '23 Aug 2020 11:59'	System	22 Aug 2020 15:05:04

US3272260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
Data entry locked.	System	22 Aug 2020 15:05:04
User entered 'Day 2'	System	22 Aug 2020 15:05:04

US3272260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:16:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-23T22:54:20', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: 'c0046f78-0923-41a9-9ac4-3f0514e5ebe9'	System	24 Aug 2020 03:54:38
User entered 'Does not interfere with activity (2)'	System	24 Aug 2020 03:54:38

US3272260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:16:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-23T22:54:23', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: 'c0046f78-0923-41a9-9ac4-3f0514e5ebe9' User entered 'No (N)'	System	24 Aug 2020 03:54:38
	System	24 Aug 2020 03:54:38

US3272260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-23T22:54:25', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: 'c0046f78-0923-41a9-9ac4-3f0514e5ebe9' User entered 'No (N)'	System	24 Aug 2020 03:54:38
	System	24 Aug 2020 03:54:38

US3272260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:16:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-23T22:54:33', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: 'c0046f78-0923-41a9-9ac4-3f0514e5ebe9'	System	24 Aug 2020 03:54:38
User entered 'None (1)'	System	24 Aug 2020 03:54:38

US3272260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-23T22:54:35', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: 'c0046f78-0923-41a9-9ac4-3f0514e5ebe9' User entered '23 Aug 2020 22:54'	System	24 Aug 2020 03:54:38
	System	24 Aug 2020 03:54:38

US3272260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
User entered '23 Aug 2020 12:00'	System	22 Aug 2020 15:05:04

US3272260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
User entered '24 Aug 2020 11:59'	System	22 Aug 2020 15:05:04

US3272260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
Data entry locked.	System	22 Aug 2020 15:05:04
User entered 'Day 3'	System	22 Aug 2020 15:05:04

US3272260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:16:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-24T22:26:53', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: 'd1b14bc1-a1b3-4bfb-8d70-f684cd9e3679'	System	25 Aug 2020 03:27:06
User entered 'None (1)'	System	25 Aug 2020 03:27:06

US3272260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:16:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-24T22:26:56', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: 'd1b14bc1-a1b3-4bfb-8d70-f684cd9e3679'	System	25 Aug 2020 03:27:06
User entered 'No (N)'	System	25 Aug 2020 03:27:06

US3272260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-24T22:26:58', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: 'd1b14bc1-a1b3-4bfb-8d70-f684cd9e3679' User entered 'No (N)'	System	25 Aug 2020 03:27:06
	System	25 Aug 2020 03:27:06

US3272260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:16:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-24T22:27:01', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: 'd1b14bc1-a1b3-4bfb-8d70-f684cd9e3679'	System	25 Aug 2020 03:27:06
User entered 'None (1)'	System	25 Aug 2020 03:27:06

US3272260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-24T22:27:03', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: 'd1b14bc1-a1b3-4bfb-8d70-f684cd9e3679'	System	25 Aug 2020 03:27:06
User entered '24 Aug 2020 22:27'	System	25 Aug 2020 03:27:06

US3272260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
User entered '24 Aug 2020 12:00'	System	22 Aug 2020 15:05:04

US3272260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
User entered '25 Aug 2020 11:59'	System	22 Aug 2020 15:05:04

US3272260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
Data entry locked.	System	22 Aug 2020 15:05:04
User entered 'Day 4'	System	22 Aug 2020 15:05:04

US3272260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:16:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-25T21:21:51', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '954a303e-256a-4ccf-a15c-55670e86fabb'	System	26 Aug 2020 02:22:07
User entered 'None (1)'	System	26 Aug 2020 02:22:07

US3272260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-25T21:21:54', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '954a303e-256a-4ccf-a15c-55670e86fabb' User entered 'No (N)'	System	26 Aug 2020 02:22:07
	System	26 Aug 2020 02:22:07

US3272260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-25T21:21:58', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '954a303e-256a-4ccf-a15c-55670e86fabb' User entered 'No (N)'	System	26 Aug 2020 02:22:07
	System	26 Aug 2020 02:22:07

US3272260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:16:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-25T21:22:01', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '954a303e-256a-4ccf-a15c-55670e86fabb' User entered 'None (1)'	System	26 Aug 2020 02:22:07
	System	26 Aug 2020 02:22:07

US3272260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-25T21:22:04', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '954a303e-256a-4ccf-a15c-55670e86fabb' User entered '25 Aug 2020 21:22'	System	26 Aug 2020 02:22:07
	System	26 Aug 2020 02:22:07

US3272260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
User entered '25 Aug 2020 12:00'	System	22 Aug 2020 15:05:04

US3272260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
User entered '26 Aug 2020 11:59'	System	22 Aug 2020 15:05:04

US3272260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
Data entry locked.	System	22 Aug 2020 15:05:04
User entered 'Day 5'	System	22 Aug 2020 15:05:04

US3272260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:16:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-26T22:11:58', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: 'e232407c-7e66-4fd8-a9cd-a20e872f5094'	System	27 Aug 2020 03:12:10
User entered 'None (1)'	System	27 Aug 2020 03:12:10

US3272260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:16:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-26T22:12:01', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: 'e232407c-7e66-4fd8-a9cd-a20e872f5094' User entered 'No (N)'	System	27 Aug 2020 03:12:10
	System	27 Aug 2020 03:12:10

US3272260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-26T22:12:03', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: 'e232407c-7e66-4fd8-a9cd-a20e872f5094' User entered 'No (N)'	System	27 Aug 2020 03:12:10
	System	27 Aug 2020 03:12:10

US3272260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:16:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-26T22:12:05', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: 'e232407c-7e66-4fd8-a9cd-a20e872f5094' User entered 'None (1)'	System	27 Aug 2020 03:12:10
	System	27 Aug 2020 03:12:10

US3272260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-26T22:12:07', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: 'e232407c-7e66-4fd8-a9cd-a20e872f5094' User entered '26 Aug 2020 22:12'	System	27 Aug 2020 03:12:10
	System	27 Aug 2020 03:12:10

US3272260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
User entered '26 Aug 2020 12:00'	System	22 Aug 2020 15:05:04

US3272260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
User entered '27 Aug 2020 11:59'	System	22 Aug 2020 15:05:04

US3272260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
Data entry locked.	System	22 Aug 2020 15:05:04
User entered 'Day 6'	System	22 Aug 2020 15:05:04

US3272260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:16:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-27T21:37:02', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: 'b3d2e910-8675-4126-ae8-19c070da478c' User entered 'None (1)'	System	28 Aug 2020 02:37:13
	System	28 Aug 2020 02:37:13

US3272260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-27T21:37:05', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: 'b3d2e910-8675-4126-ae8-19c070da478c' User entered 'No (N)'	System	28 Aug 2020 02:37:13
	System	28 Aug 2020 02:37:13

US3272260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-27T21:37:07', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: 'b3d2e910-8675-4126-ae8-19c070da478c' User entered 'No (N)'	System	28 Aug 2020 02:37:13
	System	28 Aug 2020 02:37:13

US3272260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:16:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-27T21:37:09', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: 'b3d2e910-8675-4126-ae8-19c070da478c' User entered 'None (1)'	System	28 Aug 2020 02:37:13
	System	28 Aug 2020 02:37:13

US3272260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-27T21:37:11', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: 'b3d2e910-8675-4126-ae8-19c070da478c' User entered '27 Aug 2020 21:37'	System	28 Aug 2020 02:37:13
	System	28 Aug 2020 02:37:13

US3272260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
User entered '27 Aug 2020 12:00'	System	22 Aug 2020 15:05:04

US3272260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
User entered '28 Aug 2020 11:59'	System	22 Aug 2020 15:05:04

US3272260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
Data entry locked.	System	22 Aug 2020 15:05:04
User entered 'Day 7'	System	22 Aug 2020 15:05:04

US3272260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:16:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-28T21:09:45', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: 'd45cf159-5f25-48c7-94ab-e24ff5ad4cc0'	System	29 Aug 2020 02:09:57
User entered 'None (1)'	System	29 Aug 2020 02:09:57

US3272260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-28T21:09:48', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: 'd45cf159-5f25-48c7-94ab-e24ff5ad4cc0'	System	29 Aug 2020 02:09:57
User entered 'No (N)'	System	29 Aug 2020 02:09:57

US3272260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-28T21:09:50', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: 'd45cf159-5f25-48c7-94ab-e24ff5ad4cc0' User entered 'No (N)'	System	29 Aug 2020 02:09:57
	System	29 Aug 2020 02:09:57

US3272260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:16:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-28T21:09:52', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: 'd45cf159-5f25-48c7-94ab-e24ff5ad4cc0'	System	29 Aug 2020 02:09:57
User entered 'None (1)'	System	29 Aug 2020 02:09:57

US3272260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-28T21:09:54', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: 'd45cf159-5f25-48c7-94ab-e24ff5ad4cc0'	System	29 Aug 2020 02:09:57
User entered '28 Aug 2020 21:09'	System	29 Aug 2020 02:09:57

US3272260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
User entered '28 Aug 2020 12:00'	System	22 Aug 2020 15:05:04

US3272260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
User entered '29 Aug 2020 11:59'	System	22 Aug 2020 15:05:04

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
Data entry locked.	System	22 Aug 2020 15:05:04
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Aug 2020 15:05:04

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:16:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-22T10:18:54', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '21eb9ef4-6266-4007-8ed0-986cb00a5aee' User entered 'None (0)'	System	22 Aug 2020 15:19:26
	System	22 Aug 2020 15:19:26

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:16:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-22T10:18:57', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '21eb9ef4-6266-4007-8ed0-986cb00a5aee' User entered 'None (0)'	System	22 Aug 2020 15:19:26
	System	22 Aug 2020 15:19:26

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:16:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-22T10:19:00', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '21eb9ef4-6266-4007-8ed0-986cb00a5aee' User entered 'None (0)'	System	22 Aug 2020 15:19:26
	System	22 Aug 2020 15:19:26

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:16:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-22T10:19:04', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '21eb9ef4-6266-4007-8ed0-986cb00a5aee' User entered 'None (0)'	System	22 Aug 2020 15:19:26
	System	22 Aug 2020 15:19:26

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:16:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-22T10:19:06', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '21eb9ef4-6266-4007-8ed0-986cb00a5aee' User entered 'None (0)'	System	22 Aug 2020 15:19:26
	System	22 Aug 2020 15:19:26

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:16:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-22T10:19:08', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '21eb9ef4-6266-4007-8ed0-986cb00a5aee' User entered 'None (0)'	System	22 Aug 2020 15:19:26
	System	22 Aug 2020 15:19:26

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-22T10:19:15', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '21eb9ef4-6266-4007-8ed0-986cb00a5aee' User entered 'No (N)'	System	22 Aug 2020 15:19:26
	System	22 Aug 2020 15:19:26

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:16:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-22T10:19:22', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '21eb9ef4-6266-4007-8ed0-986cb00a5aee' User entered '22 Aug 2020 10:19'	System	22 Aug 2020 15:19:26
	System	22 Aug 2020 15:19:26

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
User entered '22 Aug 2020 10:17'	System	22 Aug 2020 15:05:04

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
User entered '22 Aug 2020 12:47'	System	22 Aug 2020 15:05:04

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
Data entry locked.	System	22 Aug 2020 15:05:04
User entered 'Day 1, after vaccination (at home)'	System	22 Aug 2020 15:05:04

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:16:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-22T23:24:10', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '3919b695-1c44-4029-8702-25aa4939741a' User entered 'None (0)'	System	23 Aug 2020 04:24:40
	System	23 Aug 2020 04:24:40

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:16:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-22T23:24:15', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '3919b695-1c44-4029-8702-25aa4939741a' User entered 'None (0)'	System	23 Aug 2020 04:24:40
	System	23 Aug 2020 04:24:40

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:16:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-22T23:24:18', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '3919b695-1c44-4029-8702-25aa4939741a' User entered 'None (0)'	System	23 Aug 2020 04:24:40
	System	23 Aug 2020 04:24:40

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:16:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-22T23:24:21', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '3919b695-1c44-4029-8702-25aa4939741a' User entered 'None (0)'	System	23 Aug 2020 04:24:40
	System	23 Aug 2020 04:24:40

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:16:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-22T23:24:24', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '3919b695-1c44-4029-8702-25aa4939741a' User entered 'None (0)'	System	23 Aug 2020 04:24:40
	System	23 Aug 2020 04:24:40

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:16:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-22T23:24:27', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '3919b695-1c44-4029-8702-25aa4939741a' User entered 'None (0)'	System	23 Aug 2020 04:24:40
	System	23 Aug 2020 04:24:40

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-22T23:24:33', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '3919b695-1c44-4029-8702-25aa4939741a' User entered 'No (N)'	System	23 Aug 2020 04:24:40
	System	23 Aug 2020 04:24:40

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:16:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-22T23:24:36', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '3919b695-1c44-4029-8702-25aa4939741a' User entered '22 Aug 2020 23:24'	System	23 Aug 2020 04:24:40
	System	23 Aug 2020 04:24:40

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
User entered '22 Aug 2020 13:42'	System	22 Aug 2020 15:05:04

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
User entered '23 Aug 2020 11:59'	System	22 Aug 2020 15:05:04

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
Data entry locked.	System	22 Aug 2020 15:05:04
User entered 'Day 2'	System	22 Aug 2020 15:05:04

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:16:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-23T22:54:40', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '54fc1829-4d24-48e4-89d4-96f8105fcfa5' User entered 'None (0)'	System	24 Aug 2020 03:55:05
	System	24 Aug 2020 03:55:05

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:16:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-23T22:54:42', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '54fc1829-4d24-48e4-89d4-96f8105fcfa5' User entered 'None (0)'	System	24 Aug 2020 03:55:05
	System	24 Aug 2020 03:55:05

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:16:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-23T22:54:51', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '54fc1829-4d24-48e4-89d4-96f8105fcfa5' User entered 'None (0)'	System	24 Aug 2020 03:55:05
	System	24 Aug 2020 03:55:05

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:16:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-23T22:54:49', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '54fc1829-4d24-48e4-89d4-96f8105fcfa5' User entered 'None (0)'	System	24 Aug 2020 03:55:05
	System	24 Aug 2020 03:55:05

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:16:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-23T22:54:53', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '54fc1829-4d24-48e4-89d4-96f8105fcfa5' User entered 'None (0)'	System	24 Aug 2020 03:55:05
	System	24 Aug 2020 03:55:05

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:16:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-23T22:54:55', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '54fc1829-4d24-48e4-89d4-96f8105fcfa5' User entered 'None (0)'	System	24 Aug 2020 03:55:05
	System	24 Aug 2020 03:55:05

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-23T22:55:00', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '54fc1829-4d24-48e4-89d4-96f8105fcfa5' User entered 'No (N)'	System	24 Aug 2020 03:55:05
	System	24 Aug 2020 03:55:05

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:16:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-23T22:55:03', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '54fc1829-4d24-48e4-89d4-96f8105fcfa5'	System	24 Aug 2020 03:55:05
User entered '23 Aug 2020 22:55'	System	24 Aug 2020 03:55:05

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
User entered '23 Aug 2020 12:00'	System	22 Aug 2020 15:05:04

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
User entered '24 Aug 2020 11:59'	System	22 Aug 2020 15:05:04

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
Data entry locked.	System	22 Aug 2020 15:05:04
User entered 'Day 3'	System	22 Aug 2020 15:05:04

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:16:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-24T22:27:23', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '04c32f4a-fe3f-4cd2-8dbb-5536cae8dd97' User entered 'None (0)'	System	25 Aug 2020 03:27:41
	System	25 Aug 2020 03:27:41

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:16:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-24T22:27:21', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '04c32f4a-fe3f-4cd2-8dbb-5536cae8dd97'	System	25 Aug 2020 03:27:41
User entered 'None (0)'	System	25 Aug 2020 03:27:41

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:16:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-24T22:27:20', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '04c32f4a-fe3f-4cd2-8dbb-5536cae8dd97' User entered 'None (0)'	System	25 Aug 2020 03:27:41
	System	25 Aug 2020 03:27:41

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:16:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-24T22:27:27', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '04c32f4a-fe3f-4cd2-8dbb-5536cae8dd97' User entered 'None (0)'	System	25 Aug 2020 03:27:41
	System	25 Aug 2020 03:27:41

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:16:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-24T22:27:30', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '04c32f4a-fe3f-4cd2-8dbb-5536cae8dd97' User entered 'None (0)'	System	25 Aug 2020 03:27:41
	System	25 Aug 2020 03:27:41

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:16:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-24T22:27:32', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '04c32f4a-fe3f-4cd2-8dbb-5536cae8dd97' User entered 'None (0)'	System	25 Aug 2020 03:27:41
	System	25 Aug 2020 03:27:41

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-24T22:27:37', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '04c32f4a-fe3f-4cd2-8dbb-5536cae8dd97' User entered 'No (N)'	System	25 Aug 2020 03:27:41
	System	25 Aug 2020 03:27:41

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:16:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-24T22:27:38', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '04c32f4a-fe3f-4cd2-8dbb-5536cae8dd97' User entered '24 Aug 2020 22:27'	System	25 Aug 2020 03:27:41
	System	25 Aug 2020 03:27:41

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
User entered '24 Aug 2020 12:00'	System	22 Aug 2020 15:05:04

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
User entered '25 Aug 2020 11:59'	System	22 Aug 2020 15:05:04

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
Data entry locked.	System	22 Aug 2020 15:05:04
User entered 'Day 4'	System	22 Aug 2020 15:05:04

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:16:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-25T21:22:25', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: 'b5ce7a3f-9bc6-473f-bc0c-5c7de1c79b72'	System	26 Aug 2020 02:22:48
User entered 'No interference with activity (1)'	System	26 Aug 2020 02:22:48

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:16:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-25T21:22:28', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: 'b5ce7a3f-9bc6-473f-bc0c-5c7de1c79b72'	System	26 Aug 2020 02:22:48
User entered 'None (0)'	System	26 Aug 2020 02:22:48

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:16:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-25T21:22:31', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: 'b5ce7a3f-9bc6-473f-bc0c-5c7de1c79b72'	System	26 Aug 2020 02:22:48
User entered 'None (0)'	System	26 Aug 2020 02:22:48

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:16:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-25T21:22:34', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: 'b5ce7a3f-9bc6-473f-bc0c-5c7de1c79b72'	System	26 Aug 2020 02:22:48
User entered 'None (0)'	System	26 Aug 2020 02:22:48

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:16:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-25T21:22:36', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: 'b5ce7a3f-9bc6-473f-bc0c-5c7de1c79b72'	System	26 Aug 2020 02:22:48
User entered 'None (0)'	System	26 Aug 2020 02:22:48

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:16:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-25T21:22:38', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: 'b5ce7a3f-9bc6-473f-bc0c-5c7de1c79b72'	System	26 Aug 2020 02:22:48
User entered 'None (0)'	System	26 Aug 2020 02:22:48

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-25T21:22:44', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: 'b5ce7a3f-9bc6-473f-bc0c-5c7de1c79b72'	System	26 Aug 2020 02:22:48
User entered 'No (N)'	System	26 Aug 2020 02:22:48

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:16:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-25T21:22:46', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: 'b5ce7a3f-9bc6-473f-bc0c-5c7de1c79b72'	System	26 Aug 2020 02:22:48
User entered '25 Aug 2020 21:22'	System	26 Aug 2020 02:22:48

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
User entered '25 Aug 2020 12:00'	System	22 Aug 2020 15:05:04

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
User entered '26 Aug 2020 11:59'	System	22 Aug 2020 15:05:04

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
Data entry locked.	System	22 Aug 2020 15:05:04
User entered 'Day 5'	System	22 Aug 2020 15:05:04

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:16:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-26T22:12:12', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: 'f77de699-5e77-4b4b-a51d-b0d0885ec534'	System	27 Aug 2020 03:12:29
User entered 'No interference with activity (1)'	System	27 Aug 2020 03:12:29

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:16:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-26T22:12:14', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: 'f77de699-5e77-4b4b-a51d-b0d0885ec534'	System	27 Aug 2020 03:12:29
User entered 'None (0)'	System	27 Aug 2020 03:12:29

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:16:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-26T22:12:16', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: 'f77de699-5e77-4b4b-a51d-b0d0885ec534'	System	27 Aug 2020 03:12:29
User entered 'None (0)'	System	27 Aug 2020 03:12:29

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:16:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-26T22:12:18', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: 'f77de699-5e77-4b4b-a51d-b0d0885ec534' User entered 'None (0)'	System	27 Aug 2020 03:12:29
	System	27 Aug 2020 03:12:29

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:16:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-26T22:12:20', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: 'f77de699-5e77-4b4b-a51d-b0d0885ec534' User entered 'None (0)'	System	27 Aug 2020 03:12:29
	System	27 Aug 2020 03:12:29

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:16:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-26T22:12:21', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: 'f77de699-5e77-4b4b-a51d-b0d0885ec534' User entered 'None (0)'	System	27 Aug 2020 03:12:29
	System	27 Aug 2020 03:12:29

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-26T22:12:24', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: 'f77de699-5e77-4b4b-a51d-b0d0885ec534'	System	27 Aug 2020 03:12:29
User entered 'No (N)'	System	27 Aug 2020 03:12:29

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:16:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-26T22:12:27', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: 'f77de699-5e77-4b4b-a51d-b0d0885ec534'	System	27 Aug 2020 03:12:29
User entered '26 Aug 2020 22:12'	System	27 Aug 2020 03:12:29

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
User entered '26 Aug 2020 12:00'	System	22 Aug 2020 15:05:04

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
User entered '27 Aug 2020 11:59'	System	22 Aug 2020 15:05:04

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
Data entry locked.	System	22 Aug 2020 15:05:04
User entered 'Day 6'	System	22 Aug 2020 15:05:04

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:16:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-27T21:37:14', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '5fe76091-0918-4b41-b413-8454aa0644d3' User entered 'None (0)'	System	28 Aug 2020 02:37:33
	System	28 Aug 2020 02:37:33

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:16:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-27T21:37:17', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '5fe76091-0918-4b41-b413-8454aa0644d3' User entered 'None (0)'	System	28 Aug 2020 02:37:33
	System	28 Aug 2020 02:37:33

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:16:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-27T21:37:19', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '5fe76091-0918-4b41-b413-8454aa0644d3' User entered 'None (0)'	System	28 Aug 2020 02:37:33
	System	28 Aug 2020 02:37:33

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:16:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-27T21:37:21', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '5fe76091-0918-4b41-b413-8454aa0644d3' User entered 'None (0)'	System	28 Aug 2020 02:37:33
	System	28 Aug 2020 02:37:33

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:16:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-27T21:37:23', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '5fe76091-0918-4b41-b413-8454aa0644d3' User entered 'None (0)'	System	28 Aug 2020 02:37:33
	System	28 Aug 2020 02:37:33

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:16:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-27T21:37:24', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '5fe76091-0918-4b41-b413-8454aa0644d3' User entered 'None (0)'	System	28 Aug 2020 02:37:33
	System	28 Aug 2020 02:37:33

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-27T21:37:27', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '5fe76091-0918-4b41-b413-8454aa0644d3'	System	28 Aug 2020 02:37:33
User entered 'No (N)'	System	28 Aug 2020 02:37:33

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:16:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-27T21:37:29', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '5fe76091-0918-4b41-b413-8454aa0644d3' User entered '27 Aug 2020 21:37'	System	28 Aug 2020 02:37:33
	System	28 Aug 2020 02:37:33

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
User entered '27 Aug 2020 12:00'	System	22 Aug 2020 15:05:04

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
User entered '28 Aug 2020 11:59'	System	22 Aug 2020 15:05:04

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
Data entry locked.	System	22 Aug 2020 15:05:04
User entered 'Day 7'	System	22 Aug 2020 15:05:04

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:16:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-28T21:10:12', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '89fb0eb2-bc8d-43c7-90e5-575007beda4d' User entered 'None (0)'	System	29 Aug 2020 02:10:36
	System	29 Aug 2020 02:10:36

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:16:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-28T21:10:14', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '89fb0eb2-bc8d-43c7-90e5-575007beda4d' User entered 'None (0)'	System	29 Aug 2020 02:10:36
	System	29 Aug 2020 02:10:36

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:16:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-28T21:10:16', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '89fb0eb2-bc8d-43c7-90e5-575007beda4d' User entered 'None (0)'	System	29 Aug 2020 02:10:36
	System	29 Aug 2020 02:10:36

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:16:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-28T21:10:18', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '89fb0eb2-bc8d-43c7-90e5-575007beda4d' User entered 'None (0)'	System	29 Aug 2020 02:10:36
	System	29 Aug 2020 02:10:36

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:16:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-28T21:10:19', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '89fb0eb2-bc8d-43c7-90e5-575007beda4d' User entered 'None (0)'	System	29 Aug 2020 02:10:36
	System	29 Aug 2020 02:10:36

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:16:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-28T21:10:21', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '89fb0eb2-bc8d-43c7-90e5-575007beda4d' User entered 'None (0)'	System	29 Aug 2020 02:10:36
	System	29 Aug 2020 02:10:36

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-28T21:10:30', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '89fb0eb2-bc8d-43c7-90e5-575007beda4d' User entered 'Yes (Y)'	System	29 Aug 2020 02:10:36
	System	29 Aug 2020 02:10:36

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:16:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-08-28T21:10:33', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '89fb0eb2-bc8d-43c7-90e5-575007beda4d' User entered '28 Aug 2020 21:10'	System	29 Aug 2020 02:10:36
	System	29 Aug 2020 02:10:36

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
User entered '28 Aug 2020 12:00'	System	22 Aug 2020 15:05:04

US3272260

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
User entered '29 Aug 2020 11:59'	System	22 Aug 2020 15:05:04

US3272260

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:53:23
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:09:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 13:29:52

US3272260

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:53:23
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:09:38
User entered '29 Aug 2020'	(b) (4), (b) (6)	01 Sep 2020 13:29:52

US3272260

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:53:23
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:09:38
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	01 Sep 2020 13:29:52

US3272260

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:53:23
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:09:38
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 13:29:52

US3272260

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:53:23
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:09:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 13:29:59

US3272260

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:16:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:53:23
User entered '1'	System	01 Sep 2020 13:29:59

US3272260

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:03
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:09:52
User entered 'Yes (Y)'	Kayla Flege (b) (4)	08 Sep 2020 23:39:00
	(b) (4)	

US3272260

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:03
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:09:52
User entered '8 Sep 2020'	Kayla Flege (b) (4)	08 Sep 2020 23:39:00
	(b) (4)	

US3272260

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:03
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:09:52
User entered 'Contact Made (CONTACT MADE)'	Kayla Flege (b) (4)	08 Sep 2020 23:39:00
	(b) (4)	

US3272260

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:03
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:09:52
User entered empty.	Kayla Flege (b) (4)	08 Sep 2020 23:39:00
	(b) (4)	

US3272260

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:03
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:09:55
User entered 'Yes (Y)'	Kayla Flege (b) (4)	08 Sep 2020 23:38:49
	(b) (4)	

US3272260

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:16:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:03
User entered 'I'	System	08 Sep 2020 23:38:49

US3272260

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:30:51
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:10:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 20:52:40

US3272260

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:30:51
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:10:02
User entered '12 Sep 2020'	(b) (4), (b) (6)	14 Sep 2020 20:52:40

US3272260

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:30:51
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:10:02
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	14 Sep 2020 20:52:40

US3272260

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:30:51
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:10:02
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 20:52:40

US3272260

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:30:51
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:10:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 20:52:43

US3272260

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:16:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:30:51
User entered 'I'	System	14 Sep 2020 20:52:43

US3272260

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:16:35

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:24:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:10:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 18:56:31

US3272260

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:24:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:10:13
User entered '23 Sep 2020'	(b) (4), (b) (6)	23 Sep 2020 18:56:31

US3272260

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:24:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:10:13
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	23 Sep 2020 18:56:31

US3272260

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:16:35

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:24:16
User entered 'VISIT2'	System	23 Sep 2020 18:56:31

US3272260

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:35

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:24:16
User accepted default value 'Pre-Dose (PREDOSE)'		23 Sep 2020 20:12:06

US3272260

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:24:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:10:17
User entered 'Yes (Y)'		23 Sep 2020 20:12:06

US3272260

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:24:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:10:17
User entered '23 Sep 2020'		23 Sep 2020 20:12:06

US3272260

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:24:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:10:17
User entered '13:16'		23 Sep 2020 20:12:06

US3272260

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:24:16
User entered '23 Sep 2020 13:16'	System	23 Sep 2020 20:12:06

US3272260

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:24:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:10:17
User entered '36.6' C		23 Sep 2020 20:12:06

US3272260

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:24:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:10:17
User entered 'Oral (Oral)'		23 Sep 2020 20:12:06

US3272260

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:24:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:10:17
User entered empty.		23 Sep 2020 20:12:06

US3272260

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:24:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:10:17
User entered '65'		23 Sep 2020 20:12:06

US3272260

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:24:16
User entered 'bpm'	System	23 Sep 2020 20:12:06

US3272260

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:24:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:10:17
User entered '18'		23 Sep 2020 20:12:06

US3272260

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:24:16
User entered 'breaths/min'	System	23 Sep 2020 20:12:06

US3272260

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:24:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:10:17
User entered '139'		23 Sep 2020 20:12:06

US3272260

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:24:16
User entered 'mmHg'	System	23 Sep 2020 20:12:06

US3272260

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:35

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:24:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:10:17
User entered '89'		23 Sep 2020 20:12:06

US3272260

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:35

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:24:16
User entered 'mmHg'	System	23 Sep 2020 20:12:06

US3272260

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:35

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:24:16
User accepted default value 'Post-Dose (POSTDOSE)'		23 Sep 2020 20:12:06

US3272260

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:24:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:10:17
User entered 'No (N)'		23 Sep 2020 20:12:06

US3272260

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:24:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:10:17
User entered empty.		23 Sep 2020 20:12:06

US3272260

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:24:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:10:17
User entered empty.		23 Sep 2020 20:12:06

US3272260

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:24:16
User entered empty.	System	23 Sep 2020 20:12:06

US3272260

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:24:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:10:17
User entered empty.		23 Sep 2020 20:12:06

US3272260

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:24:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:10:17
User entered empty.		23 Sep 2020 20:12:06

US3272260

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:24:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:10:17
User entered empty.		23 Sep 2020 20:12:06

US3272260

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:24:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:10:17
User entered empty.		23 Sep 2020 20:12:06

US3272260

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:24:16
User entered empty.	System	23 Sep 2020 20:12:06

US3272260

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:24:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:10:17
User entered empty.		23 Sep 2020 20:12:06

US3272260

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:24:16
User entered empty.	System	23 Sep 2020 20:12:06

US3272260

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:24:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:10:17
User entered empty.		23 Sep 2020 20:12:06

US3272260

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:24:16
User entered empty.	System	23 Sep 2020 20:12:06

US3272260

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:24:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:10:17
User entered empty.		23 Sep 2020 20:12:06

US3272260

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:35

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:24:16
User entered empty.	System	23 Sep 2020 20:12:06

US3272260

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:16:35

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:24:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:10:21
User entered 'Yes (Y)'		23 Sep 2020 20:12:11

US3272260

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:16:35

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:24:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:10:21
User entered '23 Sep 2020'		23 Sep 2020 20:12:11

US3272260

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:16:35

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:24:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:10:25
User entered 'No (N)'		23 Sep 2020 18:57:02

US3272260

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:16:35

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:24:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:10:25
User entered 'Confirmed COVID-19 (COVID)'		23 Sep 2020 18:57:02

US3272260

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:16:35

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)	02 May 2021 12:24:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:10:25
User entered empty.		23 Sep 2020 18:57:02

US3272260

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:16:35

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:24:16
User entered empty.	System	23 Sep 2020 18:57:02

US3272260

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:16:35

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:24:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:10:25
User entered empty.		23 Sep 2020 18:57:02

US3272260

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:24:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:10:25
User entered empty.		23 Sep 2020 18:57:02

US3272260

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:24:16
User entered empty.	System	23 Sep 2020 18:57:02

US3272260

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:24:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:10:25
User entered empty.		23 Sep 2020 18:57:02

US3272260

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:24:16
DataPoint Verified.		29 Sep 2020 17:10:25
User entered empty.	System	23 Sep 2020 18:57:02

US3272260

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:16:35

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:24:16
User entered empty.	System	23 Sep 2020 18:57:02

US3272260

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:16:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:24:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:10:29
User entered 'Yes (Y)'		23 Sep 2020 20:12:27

US3272260

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:16:35

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:24:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:10:29
User entered '23 Sep 2020'		23 Sep 2020 20:12:27

US3272260

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:24:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:10:29
User entered '13:43'		23 Sep 2020 20:12:27

US3272260

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:24:16
User entered '23 Sep 2020 13:43'	System	23 Sep 2020 20:12:27

US3272260

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:16:35

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:24:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:10:33
User entered '23 Sep 2020'		23 Sep 2020 20:12:37

US3272260

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:16:35

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:24:16
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'		23 Sep 2020 20:12:37

US3272260

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:16:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:24:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:10:33
User entered 'Yes (Y)'		23 Sep 2020 20:12:37

US3272260

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:16:35

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:24:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:10:33
User entered '13:53'		23 Sep 2020 20:12:37

US3272260

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:24:16
User entered '23 Sep 2020 13:53'	System	23 Sep 2020 20:12:37

US3272260

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:16:35

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:24:16
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'		23 Sep 2020 20:12:37

US3272260

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:16:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:24:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:10:33
User entered 'No (N)'		23 Sep 2020 20:12:37

US3272260

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:16:35

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:24:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:10:33
User entered empty.		23 Sep 2020 20:12:37

US3272260

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:24:16
User entered empty.	System	23 Sep 2020 20:12:37

US3272260

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:24:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:10:37
User entered 'Yes (Y)'		23 Sep 2020 18:57:14

US3272260

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:16:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:24:16
User entered '1'	System	23 Sep 2020 18:57:14

US3272260

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:19:29
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 21:54:50

US3272260

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:19:29
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered '02 Oct 2020'	(b) (4), (b) (6)	07 Oct 2020 21:54:50

US3272260

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:19:29
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	07 Oct 2020 21:54:50

US3272260

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:19:29
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 21:54:50

US3272260

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:19:29
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 21:54:55

US3272260

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:16:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:19:29
User entered 'I'	System	07 Oct 2020 21:54:55

US3272260

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:43:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 21:55:09

US3272260

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:43:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered '07 Oct 2020'	(b) (4), (b) (6)	07 Oct 2020 21:55:09

US3272260

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:43:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	07 Oct 2020 21:55:09

US3272260

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:43:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 21:55:09

US3272260

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:43:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 21:55:15

US3272260

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:16:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:43:30
User entered 'I'	System	07 Oct 2020 21:55:15

US3272260

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:06:33
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'Yes (Y)'	Andrea Clement (b) (4)	14 Oct 2020 14:42:55

US3272260

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:06:33
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered '14 Oct 2020'	Andrea Clement (b) (4)	14 Oct 2020 14:42:55

US3272260

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:06:33
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'Contact Made (CONTACT MADE)'	Andrea Clement (b) (4)	14 Oct 2020 14:42:55

US3272260

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:06:33
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered empty.	Andrea Clement (b) (4)	14 Oct 2020 14:42:55

US3272260

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:06:33
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'Yes (Y)'	Andrea Clement (b) (4)	14 Oct 2020 14:42:58

US3272260

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:16:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:06:33
User entered 'I'	System	14 Oct 2020 14:42:58

US3272260

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:16:35

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:35:47
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Oct 2020 19:55:27

US3272260

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:35:47
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
User entered '21 Oct 2020'	(b) (4), (b) (6)	21 Oct 2020 19:55:27

US3272260

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:35:47
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	21 Oct 2020 19:55:27

US3272260

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:16:35

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:35:47
User entered 'VISIT3'	System	21 Oct 2020 19:55:27

US3272260

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:35:47
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Oct 2020 19:57:30

US3272260

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:35:47
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
User entered '21 Oct 2020'	(b) (4), (b) (6)	21 Oct 2020 19:57:30

US3272260

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:35:47
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
User entered '14:38'	(b) (4), (b) (6)	21 Oct 2020 19:57:30

US3272260

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:35:47
User entered '21 Oct 2020 14:38'	System	21 Oct 2020 19:57:30

US3272260

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:35:47
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
User entered '36.8' C	(b) (4), (b) (6)	21 Oct 2020 19:57:30

US3272260

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:35:47
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
User entered 'Oral (Oral)'	(b) (4), (b) (6)	21 Oct 2020 19:57:30

US3272260

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:35:47
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 19:57:30

US3272260

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:35:47
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
User entered '69'	(b) (4), (b) (6)	21 Oct 2020 19:57:30

US3272260

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:35:47
User entered 'bpm'	System	21 Oct 2020 19:57:30

US3272260

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:35:47
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
User entered '15'	(b) (4), (b) (6)	21 Oct 2020 19:57:30

US3272260

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:35:47
User entered 'breaths/min'	System	21 Oct 2020 19:57:30

US3272260

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:35:47
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
User entered '123'	(b) (4), (b) (6)	21 Oct 2020 19:57:30

US3272260

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:35:47
User entered 'mmHg'	System	21 Oct 2020 19:57:30

US3272260

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:35

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:35:47
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
User entered '93'	(b) (4), (b) (6)	21 Oct 2020 19:57:30

US3272260

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:35

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:35:47
User entered 'mmHg'	System	21 Oct 2020 19:57:30

US3272260

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:35

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:35:47

US3272260

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:35

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:35:47

US3272260

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:16:35

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:35:47
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Oct 2020 19:57:38

US3272260

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:16:35

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:35:47
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
User entered '21 Oct 2020'	(b) (4), (b) (6)	21 Oct 2020 19:57:38

US3272260

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:16:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:35:47
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Oct 2020 19:57:54

US3272260

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:16:35

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:35:47
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
User entered '21 Oct 2020'	(b) (4), (b) (6)	21 Oct 2020 19:57:54

US3272260

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:35:47
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
User entered '14:43' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Nov 2020 14:36:54
User entered '14:53'		21 Oct 2020 19:57:54

US3272260

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:35:47
User entered '21 Oct 2020 14:43'	System	21 Nov 2020 14:36:54
User entered '21 Oct 2020 14:53'	System	21 Oct 2020 19:57:54

US3272260

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:35:47
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Oct 2020 19:57:58

US3272260

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:16:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:35:47
User entered '1'	System	21 Oct 2020 19:57:58

US3272260

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
Data entry locked.	System	22 Aug 2020 15:05:04
User entered 'Day 64'	System	22 Aug 2020 15:05:04

US3272260

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-10-22T15:54:32', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '5d8e5438-249e-476f-903c-e85008e8287d' User entered 'No (N)'	System	22 Oct 2020 20:54:59
	System	22 Oct 2020 20:54:59

US3272260

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-10-22T15:54:50', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '5d8e5438-249e-476f-903c-e85008e8287d' User entered 'No (N)'	System	22 Oct 2020 20:54:59
	System	22 Oct 2020 20:54:59

US3272260

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-10-22T15:54:55', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '5d8e5438-249e-476f-903c-e85008e8287d' User entered '22 Oct 2020 15:54:55'	System	22 Oct 2020 20:54:59
	System	22 Oct 2020 20:54:59

US3272260

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
Data entry locked.	System	22 Aug 2020 15:05:04
User entered '22 Oct 2020 00:01'	System	22 Aug 2020 15:05:04

US3272260

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
Data entry locked.	System	22 Aug 2020 15:05:04
User entered '26 Oct 2020 23:59'	System	22 Aug 2020 15:05:04

US3272260

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
Data entry locked.	System	22 Aug 2020 15:05:04
User entered 'Day 71'	System	22 Aug 2020 15:05:04

US3272260

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-10-31T12:31:22', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: 'b3d0da0b-c48c-45a1-a393-01c58ea79c02'	System	31 Oct 2020 17:32:21
User entered 'No (N)'	System	31 Oct 2020 17:32:21

US3272260

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-10-31T12:31:26', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: 'b3d0da0b-c48c-45a1-a393-01c58ea79c02'	System	31 Oct 2020 17:32:21
User entered 'No (N)'	System	31 Oct 2020 17:32:21

US3272260

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-10-31T12:32:18', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: 'b3d0da0b-c48c-45a1-a393-01c58ea79c02' User entered '31 Oct 2020 12:32:18'	System	31 Oct 2020 17:32:21
	System	31 Oct 2020 17:32:21

US3272260

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
Data entry locked.	System	22 Aug 2020 15:05:04
User entered '29 Oct 2020 00:01'	System	22 Aug 2020 15:05:04

US3272260

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
Data entry locked.	System	22 Aug 2020 15:05:04
User entered '02 Nov 2020 23:59'	System	22 Aug 2020 15:05:04

US3272260

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
Data entry locked.	System	22 Aug 2020 15:05:04
User entered 'Day 78'	System	22 Aug 2020 15:05:04

US3272260

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-11-05T13:46:30', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '1f5bfed4-ec96-4821-af1d-0114d4a86aca'	System	05 Nov 2020 19:46:41
User entered 'No (N)'	System	05 Nov 2020 19:46:41

US3272260

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-11-05T13:46:34', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '1f5bfed4-ec96-4821-af1d-0114d4a86aca'	System	05 Nov 2020 19:46:41
User entered 'No (N)'	System	05 Nov 2020 19:46:41

US3272260

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-11-05T13:46:37', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '1f5bfed4-ec96-4821-af1d-0114d4a86aca' User entered '05 Nov 2020 13:46:37'	System	05 Nov 2020 19:46:41
	System	05 Nov 2020 19:46:41

US3272260

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
Data entry locked.	System	22 Aug 2020 15:05:04
User entered '05 Nov 2020 00:01'	System	22 Aug 2020 15:05:04

US3272260

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:23:12
Data entry locked.	System	22 Aug 2020 15:05:04
User entered '09 Nov 2020 23:59'	System	22 Aug 2020 15:05:04

US3272260

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:38
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	09 Apr 2021 22:05:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:13:50
Data entry locked.	System	22 Aug 2020 15:05:04
User entered 'Day 92'	System	22 Aug 2020 15:05:04

US3272260

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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 Apr 2021 09:13:38
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	09 Apr 2021 22:05:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:13:50

US3272260

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Have you been exposed to someone with 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 Apr 2021 09:13:38
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	09 Apr 2021 22:05:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:13:50

US3272260

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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 Apr 2021 09:13:38
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	09 Apr 2021 22:05:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:13:50

US3272260

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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 Apr 2021 09:13:38
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	09 Apr 2021 22:05:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:13:50

US3272260

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:38
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	09 Apr 2021 22:05:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:13:50

US3272260

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:38
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	09 Apr 2021 22:05:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:13:50

US3272260

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:38
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	09 Apr 2021 22:05:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:13:50

US3272260

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:38
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	09 Apr 2021 22:05:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:13:50

US3272260

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:38
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	09 Apr 2021 22:05:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:13:50

US3272260

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:38
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	09 Apr 2021 22:05:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:13:50

US3272260

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:38
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	09 Apr 2021 22:05:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:13:50

US3272260

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:38
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	09 Apr 2021 22:05:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:13:50

US3272260

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:38
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	09 Apr 2021 22:05:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:13:50

US3272260

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:38
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	09 Apr 2021 22:05:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:13:50

US3272260

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:38
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	09 Apr 2021 22:05:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:13:50

US3272260

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:38
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	09 Apr 2021 22:05:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:13:50

US3272260

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:38
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	09 Apr 2021 22:05:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:13:50

US3272260

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:38
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	09 Apr 2021 22:05:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:13:50

US3272260

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:38
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	09 Apr 2021 22:05:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:13:50

US3272260

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:38
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	09 Apr 2021 22:05:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:13:50

US3272260

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:38
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	09 Apr 2021 22:05:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:13:50

US3272260

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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 Apr 2021 09:13:38
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	09 Apr 2021 22:05:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:13:50

US3272260

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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 Apr 2021 09:13:38
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	09 Apr 2021 22:05:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:13:50

US3272260

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Please 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 Apr 2021 09:13:38
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	09 Apr 2021 22:05:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:13:50

US3272260

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:38
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	09 Apr 2021 22:05:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:13:50

US3272260

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:38
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	09 Apr 2021 22:05:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:13:50
Data entry locked.	System	22 Aug 2020 15:05:04
User entered '19 Nov 2020 00:01'	System	22 Aug 2020 15:05:04

US3272260

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:38
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	09 Apr 2021 22:05:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:13:50
Data entry locked.	System	22 Aug 2020 15:05:04
User entered '23 Nov 2020 23:59'	System	22 Aug 2020 15:05:04

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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 (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-11-27T07:43:41', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '05c09c4b-545d-4407-96ac-1ed5d55d9101' User entered 'No (N)'	System	27 Nov 2020 13:45:53

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Have you been exposed to someone with 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 (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-11-27T07:45:36', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '05c09c4b-545d-4407-96ac-1ed5d55d9101'	System	27 Nov 2020 13:45:53
User entered 'Yes (Y)'	System	27 Nov 2020 13:45:53

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-11-27T07:45:39', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '05c09c4b-545d-4407-96ac-1ed5d55d9101'	System	27 Nov 2020 13:45:53
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	27 Nov 2020 13:45:53

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A790C69E-B2CD-47A1-975A-9DD9E83629A6)', Time: '2020-11-27T07:45:44', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '05c09c4b-545d-4407-96ac-1ed5d55d9101' User entered '27 Nov 2020 07:45:44'	System	27 Nov 2020 13:45:53
	System	27 Nov 2020 13:45:53

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '23 Nov 2020 00:01'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '27 Nov 2020 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '30 Nov 2020 00:01'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '04 Dec 2020 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '07 Dec 2020 00:01'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '11 Dec 2020 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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 (A8EA8CA5-5248-4789-95D1-9AB0F5D4C6DD)', Time: '2020-12-15T17:14:27', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '4dcf4fe1-e5c6-4ee8-be31-ff80d47e738a' User entered 'No (N)'	System	15 Dec 2020 23:14:37
	System	15 Dec 2020 23:14:37

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Have you been exposed to someone with 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 (A8EA8CA5-5248-4789-95D1-9AB0F5D4C6DD)', Time: '2020-12-15T17:14:30', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '4dcf4fe1-e5c6-4ee8-be31-ff80d47e738a' User entered 'No (N)'	System	15 Dec 2020 23:14:37

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8EA8CA5-5248-4789-95D1-9AB0F5D4C6DD)', Time: '2020-12-15T17:14:33', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '4dcf4fe1-e5c6-4ee8-be31-ff80d47e738a' User entered '15 Dec 2020 17:14:33'	System	15 Dec 2020 23:14:37
	System	15 Dec 2020 23:14:37

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '14 Dec 2020 00:01'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '18 Dec 2020 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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 (A8EA8CA5-5248-4789-95D1-9AB0F5D4C6DD)', Time: '2020-12-21T06:34:55', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: 'd1358d27-cee0-4aa5-8c85-63ae2c06607d' User entered 'No (N)'	System	21 Dec 2020 12:35:04
	System	21 Dec 2020 12:35:04

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Have you been exposed to someone with 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 (A8EA8CA5-5248-4789-95D1-9AB0F5D4C6DD)', Time: '2020-12-21T06:34:58', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: 'd1358d27-cee0-4aa5-8c85-63ae2c06607d' User entered 'No (N)'	System	21 Dec 2020 12:35:04
	System	21 Dec 2020 12:35:04

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8EA8CA5-5248-4789-95D1-9AB0F5D4C6DD)', Time: '2020-12-21T06:35:01', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: 'd1358d27-cee0-4aa5-8c85-63ae2c06607d' User entered '21 Dec 2020 06:35:01'	System	21 Dec 2020 12:35:04
	System	21 Dec 2020 12:35:04

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '21 Dec 2020 00:01'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '25 Dec 2020 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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 (A8EA8CA5-5248-4789-95D1-9AB0F5D4C6DD)', Time: '2020-12-28T16:00:55', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '4a2ebb1d-98f6-4056-95d0-ed4cc683b729' User entered 'No (N)'	System	28 Dec 2020 22:01:04
	System	28 Dec 2020 22:01:04

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Have you been exposed to someone with 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 (A8EA8CA5-5248-4789-95D1-9AB0F5D4C6DD)', Time: '2020-12-28T16:00:58', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '4a2ebb1d-98f6-4056-95d0-ed4cc683b729'	System	28 Dec 2020 22:01:04
User entered 'No (N)'	System	28 Dec 2020 22:01:04

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8EA8CA5-5248-4789-95D1-9AB0F5D4C6DD)', Time: '2020-12-28T16:01:00', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '4a2ebb1d-98f6-4056-95d0-ed4cc683b729' User entered '28 Dec 2020 16:01:00'	System	28 Dec 2020 22:01:04
	System	28 Dec 2020 22:01:04

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '28 Dec 2020 00:01'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '01 Jan 2021 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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 (A8EA8CA5-5248-4789-95D1-9AB0F5D4C6DD)', Time: '2021-01-06T09:48:43', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: 'efa68b9e-a1db-4e5e-b353-968ca8da183f' User entered 'No (N)'	System	06 Jan 2021 15:48:56
	System	06 Jan 2021 15:48:56

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Have you been exposed to someone with 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 (A8EA8CA5-5248-4789-95D1-9AB0F5D4C6DD)', Time: '2021-01-06T09:48:49', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: 'efa68b9e-a1db-4e5e-b353-968ca8da183f' User entered 'No (N)'	System	06 Jan 2021 15:48:56

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8EA8CA5-5248-4789-95D1-9AB0F5D4C6DD)', Time: '2021-01-06T09:48:54', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: 'efa68b9e-a1db-4e5e-b353-968ca8da183f' User entered '06 Jan 2021 09:48:54'	System	06 Jan 2021 15:48:56
	System	06 Jan 2021 15:48:56

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '04 Jan 2021 00:01'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '08 Jan 2021 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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 (A8EA8CA5-5248-4789-95D1-9AB0F5D4C6DD)', Time: '2021-01-13T09:59:13', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '763ccb55-4686-4555-b421-ee9b48d7c8d1'	System	13 Jan 2021 15:59:20
User entered 'No (N)'	System	13 Jan 2021 15:59:20

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Have you been exposed to someone with 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 (A8EA8CA5-5248-4789-95D1-9AB0F5D4C6DD)', Time: '2021-01-13T09:59:16', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '763ccb55-4686-4555-b421-ee9b48d7c8d1'	System	13 Jan 2021 15:59:20
User entered 'No (N)'	System	13 Jan 2021 15:59:20

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8EA8CA5-5248-4789-95D1-9AB0F5D4C6DD)', Time: '2021-01-13T09:59:18', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '763ccb55-4686-4555-b421-ee9b48d7c8d1'	System	13 Jan 2021 15:59:20
User entered '13 Jan 2021 09:59:18'	System	13 Jan 2021 15:59:20

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '11 Jan 2021 00:01'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '15 Jan 2021 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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 (A8EA8CA5-5248-4789-95D1-9AB0F5D4C6DD)', Time: '2021-01-18T16:56:59', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: 'a9fd6e69-e726-4d40-81ea-6cd0cf3aad3c'	System	18 Jan 2021 22:57:07
User entered 'No (N)'	System	18 Jan 2021 22:57:07

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Have you been exposed to someone with 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 (A8EA8CA5-5248-4789-95D1-9AB0F5D4C6DD)', Time: '2021-01-18T16:57:03', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: 'a9fd6e69-e726-4d40-81ea-6cd0cf3aad3c'	System	18 Jan 2021 22:57:07
User entered 'No (N)'	System	18 Jan 2021 22:57:07

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8EA8CA5-5248-4789-95D1-9AB0F5D4C6DD)', Time: '2021-01-18T16:57:06', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: 'a9fd6e69-e726-4d40-81ea-6cd0cf3aad3c' User entered '18 Jan 2021 16:57:06'	System	18 Jan 2021 22:57:07

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '18 Jan 2021 00:01'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '22 Jan 2021 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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 (A8EA8CA5-5248-4789-95D1-9AB0F5D4C6DD)', Time: '2021-01-26T17:48:48', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '517c205e-8f2b-45d7-b9d5-424f42ce7ab8'	System	27 Jan 2021 00:58:14
User entered 'No (N)'	System	27 Jan 2021 00:58:14

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Have you been exposed to someone with 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 (A8EA8CA5-5248-4789-95D1-9AB0F5D4C6DD)', Time: '2021-01-26T17:48:51', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '517c205e-8f2b-45d7-b9d5-424f42ce7ab8'	System	27 Jan 2021 00:58:14
User entered 'No (N)'	System	27 Jan 2021 00:58:14

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8EA8CA5-5248-4789-95D1-9AB0F5D4C6DD)', Time: '2021-01-26T17:48:53', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '517c205e-8f2b-45d7-b9d5-424f42ce7ab8' User entered '26 Jan 2021 17:48:53'	System	27 Jan 2021 00:58:14
	System	27 Jan 2021 00:58:14

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '25 Jan 2021 00:01'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '29 Jan 2021 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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 (A8EA8CA5-5248-4789-95D1-9AB0F5D4C6DD)', Time: '2021-02-01T18:01:15', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: 'df0382ca-99c3-4cd7-8297-3e4ae1a80af1' User entered 'No (N)'	System	02 Feb 2021 00:02:45
	System	02 Feb 2021 00:02:45

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Have you been exposed to someone with 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 (A8EA8CA5-5248-4789-95D1-9AB0F5D4C6DD)', Time: '2021-02-01T18:01:18', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: 'df0382ca-99c3-4cd7-8297-3e4ae1a80af1' User entered 'No (N)'	System	02 Feb 2021 00:02:45
	System	02 Feb 2021 00:02:45

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8EA8CA5-5248-4789-95D1-9AB0F5D4C6DD)', Time: '2021-02-01T18:01:20', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: 'df0382ca-99c3-4cd7-8297-3e4ae1a80af1' User entered '01 Feb 2021 18:01:20'	System	02 Feb 2021 00:02:45
	System	02 Feb 2021 00:02:45

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '01 Feb 2021 00:01'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '05 Feb 2021 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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 (A8EA8CA5-5248-4789-95D1-9AB0F5D4C6DD)', Time: '2021-02-11T18:04:34', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '733790e7-25f9-4a7d-975e-6e45885049aa' User entered 'No (N)'	System	12 Feb 2021 00:09:20
	System	12 Feb 2021 00:09:20

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Have you been exposed to someone with 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 (A8EA8CA5-5248-4789-95D1-9AB0F5D4C6DD)', Time: '2021-02-11T18:04:37', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '733790e7-25f9-4a7d-975e-6e45885049aa' User entered 'No (N)'	System	12 Feb 2021 00:09:20
	System	12 Feb 2021 00:09:20

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8EA8CA5-5248-4789-95D1-9AB0F5D4C6DD)', Time: '2021-02-11T18:04:40', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '733790e7-25f9-4a7d-975e-6e45885049aa' User entered '11 Feb 2021 18:04:40'	System	12 Feb 2021 00:09:20
	System	12 Feb 2021 00:09:20

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '08 Feb 2021 00:01'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '12 Feb 2021 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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 (A8EA8CA5-5248-4789-95D1-9AB0F5D4C6DD)', Time: '2021-02-17T12:00:35', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '500a4373-942b-4c0a-aa6b-a1f410e5f4a5' User entered 'No (N)'	System	23 Feb 2021 23:41:00
	System	23 Feb 2021 23:41:00

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Have you been exposed to someone with 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 (A8EA8CA5-5248-4789-95D1-9AB0F5D4C6DD)', Time: '2021-02-17T12:00:37', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '500a4373-942b-4c0a-aa6b-a1f410e5f4a5'	System	23 Feb 2021 23:41:00
User entered 'No (N)'	System	23 Feb 2021 23:41:00

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8EA8CA5-5248-4789-95D1-9AB0F5D4C6DD)', Time: '2021-02-17T12:00:39', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '500a4373-942b-4c0a-aa6b-a1f410e5f4a5' User entered '17 Feb 2021 12:00:39'	System	23 Feb 2021 23:41:00
	System	23 Feb 2021 23:41:00

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '15 Feb 2021 00:01'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '19 Feb 2021 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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 (A8EA8CA5-5248-4789-95D1-9AB0F5D4C6DD)', Time: '2021-02-23T17:41:02-06:00', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: 'a23568fd-3a70-4411-ad81-39d818199bea' User entered 'No (N)'	System	23 Feb 2021 23:41:09
	System	23 Feb 2021 23:41:09

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Have you been exposed to someone with 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 (A8EA8CA5-5248-4789-95D1-9AB0F5D4C6DD)', Time: '2021-02-23T17:41:03-06:00', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: 'a23568fd-3a70-4411-ad81-39d818199bea' User entered 'No (N)'	System	23 Feb 2021 23:41:09
	System	23 Feb 2021 23:41:09

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8EA8CA5-5248-4789-95D1-9AB0F5D4C6DD)', Time: '2021-02-23T17:41:05-06:00', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: 'a23568fd-3a70-4411-ad81-39d818199bea' User entered '23 Feb 2021 23:41:05'	System	23 Feb 2021 23:41:09
	System	23 Feb 2021 23:41:09

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '22 Feb 2021 00:01'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '26 Feb 2021 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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 (A8EA8CA5-5248-4789-95D1-9AB0F5D4C6DD)', Time: '2021-03-01T18:44:49-06:00', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '3dcd965a-a3c0-4be2-8270-9e5bb4f60c96'	System	02 Mar 2021 00:45:10
User entered 'Yes (Y)'	System	02 Mar 2021 00:45:10

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Have you been exposed to someone with 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 (A8EA8CA5-5248-4789-95D1-9AB0F5D4C6DD)', Time: '2021-03-01T18:44:52-06:00', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '3dcd965a-a3c0-4be2-8270-9e5bb4f60c96'	System	02 Mar 2021 00:45:10
User entered 'No (N)'	System	02 Mar 2021 00:45:10

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8EA8CA5-5248-4789-95D1-9AB0F5D4C6DD)', Time: '2021-03-01T18:44:59-06:00', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '3dcd965a-a3c0-4be2-8270-9e5bb4f60c96'	System	02 Mar 2021 00:45:10
User entered 'No (N)'	System	02 Mar 2021 00:45:10

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8EA8CA5-5248-4789-95D1-9AB0F5D4C6DD)', Time: '2021-03-01T18:45:02-06:00', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '3dcd965a-a3c0-4be2-8270-9e5bb4f60c96'	System	02 Mar 2021 00:45:10
User entered 'No (N)'	System	02 Mar 2021 00:45:10

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8EA8CA5-5248-4789-95D1-9AB0F5D4C6DD)', Time: '2021-03-01T18:45:05-06:00', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '3dcd965a-a3c0-4be2-8270-9e5bb4f60c96'	System	02 Mar 2021 00:45:10
User entered '01 Mar 2021 18:45:05'	System	02 Mar 2021 00:45:10

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '01 Mar 2021 00:01'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '05 Mar 2021 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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 (A8EA8CA5-5248-4789-95D1-9AB0F5D4C6DD)', Time: '2021-03-12T08:49:48-06:00', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '62f35955-1e2e-4e48-96eb-fd31bc518364'	System	17 Mar 2021 13:58:01
User entered 'No (N)'	System	17 Mar 2021 13:58:01

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Have you been exposed to someone with 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 (A8EA8CA5-5248-4789-95D1-9AB0F5D4C6DD)', Time: '2021-03-12T08:49:51-06:00', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '62f35955-1e2e-4e48-96eb-fd31bc518364'	System	17 Mar 2021 13:58:01
User entered 'No (N)'	System	17 Mar 2021 13:58:01

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8EA8CA5-5248-4789-95D1-9AB0F5D4C6DD)', Time: '2021-03-12T08:49:54-06:00', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '62f35955-1e2e-4e48-96eb-fd31bc518364' User entered '12 Mar 2021 08:49:54'	System	17 Mar 2021 13:58:01
	System	17 Mar 2021 13:58:01

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '08 Mar 2021 00:01'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '12 Mar 2021 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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 (A8EA8CA5-5248-4789-95D1-9AB0F5D4C6DD)', Time: '2021-03-17T08:57:59-05:00', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: 'a51d4635-d8f4-4b1d-b146-e6e44e2a9e'	System	17 Mar 2021 13:58:13
User entered 'No (N)'	System	17 Mar 2021 13:58:13

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Have you been exposed to someone with 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 (A8EA8CA5-5248-4789-95D1-9AB0F5D4C6DD)', Time: '2021-03-17T08:58:07-05:00', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: 'a51d4635-d8f4-4b1d-b146-e6e44e4e2a9e'	System	17 Mar 2021 13:58:13
User entered 'No (N)'	System	17 Mar 2021 13:58:13

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8EA8CA5-5248-4789-95D1-9AB0F5D4C6DD)', Time: '2021-03-17T08:58:10-05:00', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: 'a51d4635-d8f4-4b1d-b146-e6e44e4e2a9e'	System	17 Mar 2021 13:58:13
User entered '17 Mar 2021 08:58:10'	System	17 Mar 2021 13:58:13

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '15 Mar 2021 00:01'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '19 Mar 2021 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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 (A8EA8CA5-5248-4789-95D1-9AB0F5D4C6DD)', Time: '2021-03-22T10:11:46-05:00', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '8b3da765-8402-4975-a4ca-e77ad1328ef7'	System	22 Mar 2021 15:12:04
User entered 'No (N)'	System	22 Mar 2021 15:12:04

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Have you been exposed to someone with 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 (A8EA8CA5-5248-4789-95D1-9AB0F5D4C6DD)', Time: '2021-03-22T10:11:53-05:00', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '8b3da765-8402-4975-a4ca-e77ad1328ef7'	System	22 Mar 2021 15:12:04
User entered 'No (N)'	System	22 Mar 2021 15:12:04

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8EA8CA5-5248-4789-95D1-9AB0F5D4C6DD)', Time: '2021-03-22T10:11:56-05:00', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '8b3da765-8402-4975-a4ca-e77ad1328ef7' User entered '22 Mar 2021 10:11:56'	System	22 Mar 2021 15:12:04
	System	22 Mar 2021 15:12:04

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '22 Mar 2021 00:01'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '26 Mar 2021 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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 (A8EA8CA5-5248-4789-95D1-9AB0F5D4C6DD)', Time: '2021-03-29T06:25:06-05:00', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '12cab70-05d5-4328-9b52-5547d7770f75'	System	29 Mar 2021 11:25:14
User entered 'No (N)'	System	29 Mar 2021 11:25:14

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Have you been exposed to someone with 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 (A8EA8CA5-5248-4789-95D1-9AB0F5D4C6DD)', Time: '2021-03-29T06:25:09-05:00', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '12cab70-05d5-4328-9b52-5547d7770f75'	System	29 Mar 2021 11:25:14
User entered 'No (N)'	System	29 Mar 2021 11:25:14

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8EA8CA5-5248-4789-95D1-9AB0F5D4C6DD)', Time: '2021-03-29T06:25:12-05:00', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '12cab70-05d5-4328-9b52-5547d7770f75'	System	29 Mar 2021 11:25:14
User entered '29 Mar 2021 06:25:12'	System	29 Mar 2021 11:25:14

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '29 Mar 2021 00:01'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '02 Apr 2021 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Have you been exposed to someone with 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '05 Apr 2021 00:01'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '09 Apr 2021 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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 (A8EA8CA5-5248-4789-95D1-9AB0F5D4C6DD)', Time: '2021-04-16T10:02:48-05:00', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '50b2f0a1-30ee-4a1e-8ef8-e31c307d6f91'	System	16 Apr 2021 15:02:59
User entered 'No (N)'	System	16 Apr 2021 15:02:59
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Have you been exposed to someone with 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 (A8EA8CA5-5248-4789-95D1-9AB0F5D4C6DD)', Time: '2021-04-16T10:02:54-05:00', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '50b2f0a1-30ee-4a1e-8ef8-e31c307d6f91'	System	16 Apr 2021 15:02:59
User entered 'No (N)'	System	16 Apr 2021 15:02:59
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8EA8CA5-5248-4789-95D1-9AB0F5D4C6DD)', Time: '2021-04-16T10:02:57-05:00', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '50b2f0a1-30ee-4a1e-8ef8-e31c307d6f91'	System	16 Apr 2021 15:02:59
User entered '16 Apr 2021 10:02:57'	System	16 Apr 2021 15:02:59
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '12 Apr 2021 00:01'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '16 Apr 2021 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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 (A8EA8CA5-5248-4789-95D1-9AB0F5D4C6DD)', Time: '2021-04-21T22:24:33-05:00', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: 'f8ee9a6b-ac4c-4489-93b5-497c0f3f0ae9'	System	22 Apr 2021 03:24:41
User entered 'No (N)'	System	22 Apr 2021 03:24:41
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Have you been exposed to someone with 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 (A8EA8CA5-5248-4789-95D1-9AB0F5D4C6DD)', Time: '2021-04-21T22:24:35-05:00', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: 'f8ee9a6b-ac4c-4489-93b5-497c0f3f0ae9'	System	22 Apr 2021 03:24:41
User entered 'No (N)'	System	22 Apr 2021 03:24:41
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8EA8CA5-5248-4789-95D1-9AB0F5D4C6DD)', Time: '2021-04-21T22:24:37-05:00', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: 'f8ee9a6b-ac4c-4489-93b5-497c0f3f0ae9'	System	22 Apr 2021 03:24:41
User entered '21 Apr 2021 22:24:37'	System	22 Apr 2021 03:24:41
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '19 Apr 2021 00:01'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '23 Apr 2021 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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 (A8EA8CA5-5248-4789-95D1-9AB0F5D4C6DD)', Time: '2021-04-26T20:33:27-05:00', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '29fa2181-1289-4713-b63a-c7c55eb06f2e'	System	27 Apr 2021 01:33:46
User entered 'No (N)'	System	27 Apr 2021 01:33:46
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Have you been exposed to someone with 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 (A8EA8CA5-5248-4789-95D1-9AB0F5D4C6DD)', Time: '2021-04-26T20:33:40-05:00', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '29fa2181-1289-4713-b63a-c7c55eb06f2e'	System	27 Apr 2021 01:33:46
User entered 'No (N)'	System	27 Apr 2021 01:33:46
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8EA8CA5-5248-4789-95D1-9AB0F5D4C6DD)', Time: '2021-04-26T20:33:43-05:00', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '29fa2181-1289-4713-b63a-c7c55eb06f2e'	System	27 Apr 2021 01:33:46
User entered '26 Apr 2021 20:33:43'	System	27 Apr 2021 01:33:46
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '26 Apr 2021 00:01'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '30 Apr 2021 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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 (A8EA8CA5-5248-4789-95D1-9AB0F5D4C6DD)', Time: '2021-05-03T00:02:35-05:00', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: 'f61ac02f-a0d2-4e25-b944-e1befbd73032'	System	03 May 2021 05:02:46
User entered 'No (N)'	System	03 May 2021 05:02:46
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Have you been exposed to someone with 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 (A8EA8CA5-5248-4789-95D1-9AB0F5D4C6DD)', Time: '2021-05-03T00:02:38-05:00', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: 'f61ac02f-a0d2-4e25-b944-e1befbd73032'	System	03 May 2021 05:02:46
User entered 'No (N)'	System	03 May 2021 05:02:46
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8EA8CA5-5248-4789-95D1-9AB0F5D4C6DD)', Time: '2021-05-03T00:02:40-05:00', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: 'f61ac02f-a0d2-4e25-b944-e1befbd73032'	System	03 May 2021 05:02:46
User entered '03 May 2021 00:02:40'	System	03 May 2021 05:02:46
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '03 May 2021 00:01'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '07 May 2021 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Have you been exposed to someone with 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '10 May 2021 00:01'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '14 May 2021 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Have you been exposed to someone with 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

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US3272260

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '17 May 2021 00:01'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '21 May 2021 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Have you been exposed to someone with 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	09 Apr 2021 22:05:30
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US3272260

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	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Please 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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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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '24 May 2021 00:01'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '28 May 2021 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Have you been exposed to someone with 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

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	09 Apr 2021 22:05:30
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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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US3272260

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '31 May 2021 00:01'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '04 Jun 2021 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
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US3272260

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	09 Apr 2021 22:05:30
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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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[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	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

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Generated On: 11 Aug 2021 22:16:35

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

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[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

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Generated On: 11 Aug 2021 22:16:35

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

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	09 Apr 2021 22:05:30
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US3272260

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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

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	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

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[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

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[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

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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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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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '07 Jun 2021 00:01'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '11 Jun 2021 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 01:13:50

US3272260

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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US3272260

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)
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US3272260

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	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

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Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
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US3272260

Folder: New Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Body aches](#)

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DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

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	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

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[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '14 Jun 2021 00:01'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '18 Jun 2021 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Have you been exposed to someone with 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	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	09 Apr 2021 22:05:30
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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?](#)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '21 Jun 2021 00:01'	System	20 Nov 2020 01:13:50

US3272260

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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '25 Jun 2021 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

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US3272260

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	09 Apr 2021 22:05:30
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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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[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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US3272260

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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

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[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

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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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

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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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

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[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

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[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

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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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '28 Jun 2021 00:01'	System	20 Nov 2020 01:13:50

US3272260

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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '02 Jul 2021 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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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US3272260

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)
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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	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

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	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

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[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '05 Jul 2021 00:01'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '09 Jul 2021 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Have you been exposed to someone with 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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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US3272260

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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US3272260

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '12 Jul 2021 00:01'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '16 Jul 2021 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Have you been exposed to someone with 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	09 Apr 2021 22:05:30
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US3272260

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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US3272260

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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	09 Apr 2021 22:05:30
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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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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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '19 Jul 2021 00:01'	System	20 Nov 2020 01:13:50

US3272260

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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '23 Jul 2021 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Have you been exposed to someone with 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	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

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US3272260

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

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US3272260

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '26 Jul 2021 00:01'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '30 Jul 2021 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Have you been exposed to someone with 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	09 Apr 2021 22:05:30
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US3272260

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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US3272260

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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

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	09 Apr 2021 22:05:30
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US3272260

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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[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '02 Aug 2021 00:01'	System	20 Nov 2020 01:13:50

US3272260

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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '06 Aug 2021 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Have you been exposed to someone with 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	09 Apr 2021 22:05:30
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US3272260

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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US3272260

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	09 Apr 2021 22:05:30
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US3272260

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	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

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	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

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	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Body aches](#)

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DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

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[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

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	09 Apr 2021 22:05:30
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US3272260

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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Please 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '09 Aug 2021 00:01'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '13 Aug 2021 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

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DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Have you been exposed to someone with 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	09 Apr 2021 22:05:30
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US3272260

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.](#)

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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Please 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '16 Aug 2021 00:01'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '20 Aug 2021 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

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TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
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US3272260

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	09 Apr 2021 22:05:30
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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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[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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DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

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Generated On: 11 Aug 2021 22:16:35

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

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US3272260

Folder: New Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

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[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

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[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

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[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

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[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

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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[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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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '23 Aug 2021 00:01'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '27 Aug 2021 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 01:13:50

US3272260

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?](#)

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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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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?](#)

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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Fever (Temperature \geq 100.4°F/38°C)

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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Cough](#)

Audit	User	Time (GMT)
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Shortness of breath](#)

Audit	User	Time (GMT)
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Muscle aches](#)

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US3272260

Folder: New Safety Follow Up Diary (1)

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[Body aches](#)

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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Headache](#)

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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Please 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '30 Aug 2021 00:01'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '03 Sep 2021 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Have you been exposed to someone with 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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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US3272260

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '06 Sep 2021 00:01'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '10 Sep 2021 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Have you been exposed to someone with 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	09 Apr 2021 22:05:30
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US3272260

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	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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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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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[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '13 Sep 2021 00:01'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '17 Sep 2021 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Have you been exposed to someone with 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	09 Apr 2021 22:05:30
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US3272260

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.](#)

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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
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US3272260

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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US3272260

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '20 Sep 2021 00:01'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '24 Sep 2021 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Have you been exposed to someone with 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

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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US3272260

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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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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

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	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	09 Apr 2021 22:05:30
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US3272260

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	09 Apr 2021 22:05:30
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Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '27 Sep 2021 00:01'	System	20 Nov 2020 01:13:50

US3272260

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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '01 Oct 2021 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

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TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Have you been exposed to someone with 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	09 Apr 2021 22:05:30
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US3272260

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?](#)

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US3272260

Folder: New Safety Follow Up Diary (1)

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Generated On: 11 Aug 2021 22:16:35

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Fatigue](#)

Audit	User	Time (GMT)
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US3272260

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	09 Apr 2021 22:05:30
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US3272260

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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

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	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Congestion](#)

Audit	User	Time (GMT)
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Runny nose](#)

Audit	User	Time (GMT)
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Diarrhea](#)

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DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

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DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '04 Oct 2021 00:01'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '08 Oct 2021 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Have you been exposed to someone with 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Please 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Please 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

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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US3272260

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

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US3272260

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '11 Oct 2021 00:01'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '15 Oct 2021 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Have you been exposed to someone with 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	09 Apr 2021 22:05:30
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US3272260

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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US3272260

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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	09 Apr 2021 22:05:30
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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	09 Apr 2021 22:05:30
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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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '18 Oct 2021 00:01'	System	20 Nov 2020 01:13:50

US3272260

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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '22 Oct 2021 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
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US3272260

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	09 Apr 2021 22:05:30
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US3272260

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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US3272260

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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '25 Oct 2021 00:01'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '29 Oct 2021 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Have you been exposed to someone with 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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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US3272260

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](#)

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US3272260

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '01 Nov 2021 00:01'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '05 Nov 2021 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Have you been exposed to someone with 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	09 Apr 2021 22:05:30
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US3272260

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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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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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[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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[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '08 Nov 2021 00:01'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '12 Nov 2021 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Have you been exposed to someone with 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	09 Apr 2021 22:05:30
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Folder: New Safety Follow Up Diary (1)

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US3272260

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?](#)

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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '15 Nov 2021 00:01'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '19 Nov 2021 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Have you been exposed to someone with 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

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US3272260

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '22 Nov 2021 00:01'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '26 Nov 2021 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Have you been exposed to someone with 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

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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[Date and time of submission](#)

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DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '29 Nov 2021 00:01'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '03 Dec 2021 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Have you been exposed to someone with 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '06 Dec 2021 00:01'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '10 Dec 2021 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Have you been exposed to someone with 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

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	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '13 Dec 2021 00:01'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '17 Dec 2021 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Have you been exposed to someone with 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Please 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '20 Dec 2021 00:01'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '24 Dec 2021 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Have you been exposed to someone with 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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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[Date and time of submission](#)

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US3272260

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '27 Dec 2021 00:01'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '31 Dec 2021 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Have you been exposed to someone with 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	09 Apr 2021 22:05:30
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US3272260

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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US3272260

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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

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	09 Apr 2021 22:05:30
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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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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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '03 Jan 2022 00:01'	System	20 Nov 2020 01:13:50

US3272260

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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '07 Jan 2022 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	31 Mar 2021 18:23:02

US3272260

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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Folder: New Safety Follow Up Diary (1)

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US3272260

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	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

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[Chills](#)

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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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Audit	User	Time (GMT)
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '10 Jan 2022 00:01'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '14 Jan 2022 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Have you been exposed to someone with 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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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[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '17 Jan 2022 00:01'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '21 Jan 2022 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Have you been exposed to someone with 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	09 Apr 2021 22:05:30
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US3272260

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	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

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	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

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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US3272260

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '24 Jan 2022 00:01'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '28 Jan 2022 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Have you been exposed to someone with 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '31 Jan 2022 00:01'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '04 Feb 2022 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Have you been exposed to someone with 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Please 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
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US3272260

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	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '07 Feb 2022 00:01'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '11 Feb 2022 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Have you been exposed to someone with 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Please 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	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '14 Feb 2022 00:01'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '18 Feb 2022 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Have you been exposed to someone with 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

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Generated On: 11 Aug 2021 22:16:35

[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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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '21 Feb 2022 00:01'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '25 Feb 2022 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Have you been exposed to someone with 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	09 Apr 2021 22:05:30
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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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[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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DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

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	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

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[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

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[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

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[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

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[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

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Generated On: 11 Aug 2021 22:16:35

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

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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[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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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '28 Feb 2022 00:01'	System	20 Nov 2020 01:13:50

US3272260

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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '04 Mar 2022 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Have you been exposed to someone with 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	09 Apr 2021 22:05:30
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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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[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Cough](#)

Audit	User	Time (GMT)
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US3272260

Folder: New Safety Follow Up Diary (1)

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[Shortness of breath](#)

Audit	User	Time (GMT)
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US3272260

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Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '07 Mar 2022 00:01'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '11 Mar 2022 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Have you been exposed to someone with 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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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DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

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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US3272260

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '14 Mar 2022 00:01'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '18 Mar 2022 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Have you been exposed to someone with 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	09 Apr 2021 22:05:30
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US3272260

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	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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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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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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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '21 Mar 2022 00:01'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '25 Mar 2022 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Have you been exposed to someone with 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '28 Mar 2022 00:01'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '01 Apr 2022 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Have you been exposed to someone with 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Please 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

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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US3272260

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	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '04 Apr 2022 00:01'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '08 Apr 2022 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Have you been exposed to someone with 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '11 Apr 2022 00:01'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '15 Apr 2022 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Have you been exposed to someone with 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
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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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '18 Apr 2022 00:01'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '22 Apr 2022 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Have you been exposed to someone with 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

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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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	09 Apr 2021 22:05:30
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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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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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '25 Apr 2022 00:01'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '29 Apr 2022 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Have you been exposed to someone with 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

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.](#)

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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '02 May 2022 00:01'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '06 May 2022 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Have you been exposed to someone with 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

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	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

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US3272260

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '09 May 2022 00:01'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '13 May 2022 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Have you been exposed to someone with 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Please 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	09 Apr 2021 22:05:30
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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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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](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '16 May 2022 00:01'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '20 May 2022 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Have you been exposed to someone with 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Please 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
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US3272260

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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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

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DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '23 May 2022 00:01'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '27 May 2022 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Have you been exposed to someone with 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	09 Apr 2021 22:05:30
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US3272260

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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US3272260

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	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

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	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

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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[Please 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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[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '30 May 2022 00:01'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '03 Jun 2022 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

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Generated On: 11 Aug 2021 22:16:35

[Have you been exposed to someone with 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	09 Apr 2021 22:05:30
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US3272260

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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US3272260

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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

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Generated On: 11 Aug 2021 22:16:35

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

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	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '06 Jun 2022 00:01'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '10 Jun 2022 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Have you been exposed to someone with 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

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.](#)

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DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	09 Apr 2021 22:05:30
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US3272260

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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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '13 Jun 2022 00:01'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '17 Jun 2022 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

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Generated On: 11 Aug 2021 22:16:35

[Have you been exposed to someone with 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	09 Apr 2021 22:05:30
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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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US3272260

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	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

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[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

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[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

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	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

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[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

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	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

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[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

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[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

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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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '20 Jun 2022 00:01'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '24 Jun 2022 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

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US3272260

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)
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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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '27 Jun 2022 00:01'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '01 Jul 2022 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Have you been exposed to someone with 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
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US3272260

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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US3272260

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '04 Jul 2022 00:01'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '08 Jul 2022 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Have you been exposed to someone with 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

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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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

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](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '11 Jul 2022 00:01'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '15 Jul 2022 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Have you been exposed to someone with 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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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[Date and time of submission](#)

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US3272260

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '18 Jul 2022 00:01'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '22 Jul 2022 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Have you been exposed to someone with 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	09 Apr 2021 22:05:30
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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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US3272260

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	09 Apr 2021 22:05:30
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US3272260

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	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

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[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

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[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

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[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

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[Vomiting](#)

Audit	User	Time (GMT)
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US3272260

Folder: New Safety Follow Up Diary (1)

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[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

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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[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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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '25 Jul 2022 00:01'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '29 Jul 2022 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

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TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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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US3272260

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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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?](#)

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US3272260

Folder: New Safety Follow Up Diary (1)

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Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Cough](#)

Audit	User	Time (GMT)
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US3272260

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	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Difficulty breathing](#)

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DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Fatigue](#)

Audit	User	Time (GMT)
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

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	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Headache](#)

Audit	User	Time (GMT)
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US3272260

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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[New loss of smell](#)

Audit	User	Time (GMT)
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

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	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Diarrhea](#)

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DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '01 Aug 2022 00:01'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '05 Aug 2022 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

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US3272260

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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US3272260

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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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

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Generated On: 11 Aug 2021 22:16:35

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

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.](#)

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DataPoint Activated.	System	09 Apr 2021 22:05:30
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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '08 Aug 2022 00:01'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '12 Aug 2022 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

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TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

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Generated On: 11 Aug 2021 22:16:35

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

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US3272260

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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US3272260

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[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

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Folder: New Safety Follow Up Diary (1)

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[Chills](#)

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US3272260

Folder: New Safety Follow Up Diary (1)

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[Cough](#)

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US3272260

Folder: New Safety Follow Up Diary (1)

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[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

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[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

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[Fatigue](#)

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US3272260

Folder: New Safety Follow Up Diary (1)

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[Muscle aches](#)

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DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

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[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

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[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

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[New loss of smell](#)

Audit	User	Time (GMT)
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Folder: New Safety Follow Up Diary (1)

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[Sore throat](#)

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[Congestion](#)

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US3272260

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[Runny nose](#)

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US3272260

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[Nausea](#)

Audit	User	Time (GMT)
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US3272260

Folder: New Safety Follow Up Diary (1)

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[Vomiting](#)

Audit	User	Time (GMT)
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US3272260

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[Diarrhea](#)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '15 Aug 2022 00:01'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '19 Aug 2022 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 01:13:50

US3272260

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?](#)

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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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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)
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US3272260

Folder: New Safety Follow Up Diary (1)

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Generated On: 11 Aug 2021 22:16:35

Fever (Temperature \geq 100.4°F/38°C)

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Folder: New Safety Follow Up Diary (1)

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[Chills](#)

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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Cough](#)

Audit	User	Time (GMT)
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Shortness of breath](#)

Audit	User	Time (GMT)
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US3272260

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	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

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	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

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[Body aches](#)

Audit	User	Time (GMT)
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Please 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '22 Aug 2022 00:01'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '26 Aug 2022 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Have you been exposed to someone with 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Please 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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US3272260

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '29 Aug 2022 00:01'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '02 Sep 2022 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Have you been exposed to someone with 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

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	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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)

Form: Safety Follow Up Diary

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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	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '05 Sep 2022 00:01'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '09 Sep 2022 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Have you been exposed to someone with 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

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	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '12 Sep 2022 00:01'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '16 Sep 2022 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Have you been exposed to someone with 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

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	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

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Audit	User	Time (GMT)
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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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '19 Sep 2022 00:01'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '23 Sep 2022 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Have you been exposed to someone with 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

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.](#)

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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

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	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

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.](#)

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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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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '26 Sep 2022 00:01'	System	20 Nov 2020 01:13:50

US3272260

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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '30 Sep 2022 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Have you been exposed to someone with 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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Folder: New Safety Follow Up Diary (1)

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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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

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[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

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[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

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[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

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.](#)

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US3272260

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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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '03 Oct 2022 00:01'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '07 Oct 2022 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

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TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

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

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US3272260

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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Folder: New Safety Follow Up Diary (1)

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Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
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US3272260

Folder: New Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

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[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

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[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

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[Muscle aches](#)

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DataPoint Activated.	System	09 Apr 2021 22:05:30
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Folder: New Safety Follow Up Diary (1)

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[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

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Folder: New Safety Follow Up Diary (1)

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

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Folder: New Safety Follow Up Diary (1)

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[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

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Folder: New Safety Follow Up Diary (1)

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[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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[Sore throat](#)

Audit	User	Time (GMT)
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[Congestion](#)

Audit	User	Time (GMT)
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[Runny nose](#)

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[Nausea](#)

Audit	User	Time (GMT)
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US3272260

Folder: New Safety Follow Up Diary (1)

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[Vomiting](#)

Audit	User	Time (GMT)
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US3272260

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[Diarrhea](#)

Audit	User	Time (GMT)
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[Patient Cloud Open Date & Time](#)

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DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '10 Oct 2022 00:01'	System	20 Nov 2020 01:13:50

US3272260

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '14 Oct 2022 23:59'	System	20 Nov 2020 01:13:50

US3272260

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TIMEPOINT

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DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

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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?](#)

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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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US3272260

Folder: New Safety Follow Up Diary (1)

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Fever (Temperature \geq 100.4°F/38°C)

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US3272260

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[Chills](#)

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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Cough](#)

Audit	User	Time (GMT)
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US3272260

Folder: New Safety Follow Up Diary (1)

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[Shortness of breath](#)

Audit	User	Time (GMT)
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US3272260

Folder: New Safety Follow Up Diary (1)

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[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
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US3272260

Folder: New Safety Follow Up Diary (1)

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[Fatigue](#)

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US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Muscle aches](#)

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[Body aches](#)

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US3272260

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[Headache](#)

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US3272260

Folder: New Safety Follow Up Diary (1)

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[New loss of taste](#)

Audit	User	Time (GMT)
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DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '17 Oct 2022 00:01'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '21 Oct 2022 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Have you been exposed to someone with 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Please 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

Please 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	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '24 Oct 2022 00:01'	System	20 Nov 2020 01:13:50

US3272260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	09 Apr 2021 22:05:30
DataPoint Inactivated.	System	31 Mar 2021 18:23:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:13:50
Amendment Manager: User entered '28 Oct 2022 23:59'	System	20 Nov 2020 01:13:50

US3272260

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:16:35

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8EA8CA5-5248-4789-95D1-9AB0F5D4C6DD)', Time: '2021-03-01T18:45:18-06:00', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '8e634861-f7aa-4cf2-9c49-06b56ddeb7fa' User entered 'No (N)'	System	02 Mar 2021 00:45:26
	System	02 Mar 2021 00:45:26

US3272260

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:16:35

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:13:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8EA8CA5-5248-4789-95D1-9AB0F5D4C6DD)', Time: '2021-03-01T18:45:22-06:00', User OID: 'PatientReportedOutcome (US3272260)', ODM File OID: '8e634861-f7aa-4cf2-9c49-06b56ddeb7fa' User entered '01 Mar 2021 18:45:22'	System	02 Mar 2021 00:45:26
	System	02 Mar 2021 00:45:26

US3272260

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:36:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Nov 2020 14:00:47

US3272260

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:36:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered '20 Nov 2020'	(b) (4), (b) (6)	21 Nov 2020 14:00:47

US3272260

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:36:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	21 Nov 2020 14:00:47

US3272260

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:36:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered empty.	(b) (4), (b) (6)	21 Nov 2020 14:00:47

US3272260

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:36:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Feb 2021 22:12:00
User closed query 'Data is required. Please complete.' (Site from System).		24 Nov 2020 16:08:18
Query 'Data is required. Please complete.' answered with 'visit hasnt occured' (Site from System).	Kayla Flege (b) (4)	19 Nov 2020 22:57:09
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Nov 2020 15:35:18
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	07 Nov 2020 15:35:18
User entered 'Yes (Y)'		07 Nov 2020 15:35:04

US3272260

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:16:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:36:06
User entered '1'	System	01 Feb 2021 22:12:00
User entered empty.	System	07 Nov 2020 15:35:18
User entered '1'	System	07 Nov 2020 15:35:04

US3272260

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:36:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'Yes (Y)'	Ashley Bell (b) (4)	31 Mar 2021 18:19:56

US3272260

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:35

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:36:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered '22 Dec 2020'	Ashley Bell (b) (4)	31 Mar 2021 18:19:56

US3272260

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:36:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'Contact Made (CONTACT MADE)'	Ashley Bell (b) (4)	31 Mar 2021 18:19:56

US3272260

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:36:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered empty.	Ashley Bell (b) (4)	31 Mar 2021 18:19:56

US3272260

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:36:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Feb 2021 22:12:09

US3272260

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:16:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:36:14
User entered 'I'	System	01 Feb 2021 22:12:09

US3272260

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Feb 2021 22:12:27

US3272260

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:35

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User closed query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded 09FEB2021 under Participant Decision Visit / OL-D1 in PPD central lab, however same is missing in EDC. Please reconcile the data and update as appropriate. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 07:10:56
Query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded 09FEB2021 under Participant Decision Visit / OL-D1 in PPD central lab, however same is missing in EDC. Please reconcile the data and update as appropriate. Else clarify, thank you.' answered with 'data in edc' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 18:02:00
User opened query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded 09FEB2021 under Participant Decision Visit / OL-D1 in PPD central lab, however same is missing in EDC. Please reconcile the data and update as appropriate. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 09:28:08
User entered '22 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Feb 2021 20:24:02
User entered '27 Jan 2021'		01 Feb 2021 22:12:27

US3272260

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	01 Feb 2021 22:12:27

US3272260

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered empty.	(b) (4), (b) (6)	01 Feb 2021 22:12:27

US3272260

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 09FEB2021 is recorded under Participant Decision Visit OL-D1/OL-1 visit in PPD Central Lab, however the same is missing in EDC. Please review and update the sample data in EDC as appropriate. Else Clarify, Thank you' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 07:47:36
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 09FEB2021 is recorded under Participant Decision Visit OL-D1/OL-1 visit in PPD Central Lab, however the same is missing in EDC. Please review and update the sample data in EDC as appropriate. Else Clarify, Thank you' answered with 'data in edc' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 18:01:32
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 09FEB2021 is recorded under Participant Decision Visit OL-D1/OL-1 visit in PPD Central Lab, however the same is missing in EDC. Please review and update the sample data in EDC as appropriate. Else Clarify, Thank you' (Site from DM).		22 Feb 2021 11:04:43
User entered 'Yes (Y)'		01 Feb 2021 22:12:16

US3272260

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:16:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:59
User entered 'I'	System	01 Feb 2021 22:12:16

US3272260

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:17:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Feb 2021 20:21:28

US3272260

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:35

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:17:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
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	09 Apr 2021 22:05:30
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	31 Mar 2021 18:23:02
User entered '22 Feb 2021'	(b) (4), (b) (6)	23 Feb 2021 20:21:28

US3272260

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:17:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	23 Feb 2021 20:21:28

US3272260

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:17:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 20:21:28

US3272260

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:17:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'No (N)' reason for change: Data Entry Error	Ashley Bell (b) (4)	31 Mar 2021 18:21:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Feb 2021 20:21:32

US3272260

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:16:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:17:05
User entered empty.	System	31 Mar 2021 18:21:43
User entered 'I'	System	23 Feb 2021 20:21:32

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:16:35

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:37
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User closed query 'Per GCL Lab Recon: Re-query: Saliva: Response noted, however samples dated 31AUG2020 and 01SEP2020 for Day 3 and Day 5 is reported under Illness visit in PPD central lab. However, saliva log is not completed in EDC. Please complete if applicable, else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 16:01:03
User closed query 'Please reconcile and enter the following missing pages: 1. Severity page 2. Illness Day 1 visit 3. Saliva log still not entered despite query response to DM' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 00:58:57
Query 'Please reconcile and enter the following missing pages: 1. Severity page 2. Illness Day 1 visit 3. Saliva log still not entered despite query response to DM' answered with 'UPDATED' (Site from CRA).	(b) (4), (b) (6)	09 Nov 2020 22:41:18
User opened query 'Please reconcile and enter the following missing pages: 1. Severity page 2. Illness Day 1 visit 3. Saliva log still not entered despite query response to DM' (Site from CRA).	(b) (4), (b) (6)	07 Nov 2020 04:00:39
Query 'Per GCL Lab Recon: Re-query: Saliva: Response noted, however samples dated 31AUG2020 and 01SEP2020 for Day 3 and Day 5 is reported under Illness visit in PPD central lab. However, saliva log is not completed in EDC. Please complete if applicable, else clarify. Thank you.' answered with 'updated' (Site from DM).	Kayla Flege (b) (4) (b) (4)	30 Oct 2020 20:13:40

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Folder: Covid-19 Assessment 28 Aug 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:16:35

[Date of Contact](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Recon: Re-query: Saliva: Response noted, however samples dated 31AUG2020 and 01SEP2020 for Day 3 and Day 5 is reported under Illness visit in PPD central lab. However, saliva log is not completed in EDC. Please complete if applicable, else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 08:16:42
Query 'Per GCL Lab Reconciliation: Re-query: Response noted, however samples dated 31AUG2020 and 01SEP2020 for Day 3 and Day 5 is reported under Illness visit in PPD central lab. However, saliva log is not completed in EDC. Please complete if applicable, else clarify. Thank you.' canceled (Site from DM).		29 Oct 2020 08:16:22
User opened query 'Per GCL Lab Reconciliation: Re-query: Response noted, however samples dated 31AUG2020 and 01SEP2020 for Day 3 and Day 5 is reported under Illness visit in PPD central lab. However, saliva log is not completed in EDC. Please complete if applicable, else clarify. Thank you.' (Site from DM).		29 Oct 2020 08:16:13
User closed query 'Per GCL Lab Reconciliation: Saliva Samples reported under Illness visit is dated in PPD Central lab. Please reconcile and update. Else clarify, thank you' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 08:16:13
Query 'Per GCL Lab Reconciliation: Saliva Samples reported under Illness visit is dated in PPD Central lab. Please reconcile and update. Else clarify, thank you' answered with 'date correct' (Site from DM).		28 Oct 2020 20:36:55
User opened query 'Per GCL Lab Reconciliation: Saliva Samples reported under Illness visit is dated in PPD Central lab. Please reconcile and update. Else clarify, thank you' (Site from DM).		25 Oct 2020 21:08:19
DataPoint Verified.		29 Sep 2020 16:51:11
User entered '28 Aug 2020' reason for change: Data Entry Error	Kayla Flege (b) (4)	14 Sep 2020 20:20:36
User entered '02 Sep 2020'	(b) (4), (b) (6)	02 Sep 2020 14:53:24

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:16:35

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:37
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:51:11
User entered '17:00'		02 Sep 2020 14:53:24

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:16:35

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:37
User entered '28 Aug 2020 17:00'	System	14 Sep 2020 20:20:36
User entered '02 Sep 2020 17:00'	System	02 Sep 2020 14:53:24

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:16:35

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:37
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:51:11
User entered 'Convalescent Tele-visit (Convalescent Tele-visit)'	(b) (4), (b) (6)	02 Sep 2020 14:53:24

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:16:35

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:37
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:51:11
User entered 'Yes (Y)' reason for change: Data Entry Error	Kayla Flege (b) (4)	14 Sep 2020 20:20:36
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 14:53:24

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:16:35

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'Day 1 (Day 1)'	Kayla Flege (b) (4)	14 Sep 2020 20:22:24

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:16:35

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User closed query 'Per CDM: Please confirm initial start date of symptoms and Contact date are the same (28AUG2020) or update accordingly.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 01:58:44
Query 'Per CDM: Please confirm initial start date of symptoms and Contact date are the same (28AUG2020) or update accordingly.' answered with 'updated' (Site from DM).		09 Nov 2020 22:42:32
DataPoint Un-verified.		09 Nov 2020 22:42:24
User entered '26 Aug 2020' reason for change: Data Entry Error		09 Nov 2020 22:42:24
User opened query 'Per CDM: Please confirm initial start date of symptoms and Contact date are the same (28AUG2020) or update accordingly.' (Site from DM).		09 Nov 2020 02:54:45
DataPoint Verified.		29 Sep 2020 16:55:10
User entered '28 Aug 2020'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:22:24

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:16:35

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered '0'	Kayla Flege (b) (4)	14 Sep 2020 20:22:24
	(b) (4)	

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:16:35

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered '98'	Kayla Flege (b) (4)	14 Sep 2020 20:22:24
	(b) (4)	

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:16:35

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User entered '%'	System	14 Sep 2020 20:22:24

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:16:35

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered '36.5' C	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:22:24

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:16:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:22:24

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:16:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:22:24

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:16:35

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:22:24

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:16:35

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:22:24

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:16:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:22:24

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:16:35

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:22:24

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:16:35

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:22:24

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:16:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'Mild (Mild)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:22:24

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:16:35

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:22:24

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:16:35

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:22:24

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:16:35

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'Mild (Mild)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:22:24

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:16:35

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:22:24

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:16:35

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:22:24

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:16:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:22:24

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:22:24

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:16:35

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:22:24

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:16:35

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'Day 4 (Day 4)' reason for change: Data Entry Error	Kayla Flege (b) (4)	11 Dec 2020 15:33:00
User entered 'Day 2 (Day 2)'	Kayla Flege (b) (4)	14 Sep 2020 20:23:37

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:16:35

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered '29 Aug 2020'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:23:37

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:16:35

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered '0'	Kayla Flege (b) (4)	14 Sep 2020 20:23:37
	(b) (4)	

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:16:35

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered '99'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:23:37

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:16:35

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User entered '%'	System	14 Sep 2020 20:23:37

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:16:35

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered '98.4' F	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:23:37

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:16:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:23:37

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:16:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:23:37

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:16:35

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4)	14 Sep 2020 20:23:37
	(b) (4)	

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:16:35

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:23:37

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:16:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:23:37

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:16:35

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:23:37

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:16:35

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:23:37

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:16:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'None (None)' reason for change: Data Entry Error	Kayla Flege (b) (4)	11 Dec 2020 15:34:04
User closed query 'Should this be yes? Review and update as applicable.' (Site from CRA).	(b) (4), (b) (6)	07 Nov 2020 04:00:49
Query 'Should this be yes? Review and update as applicable.' answered with 'data is correct' (Site from CRA).		30 Sep 2020 17:21:45
User entered 'Mild (Mild)' reason for change: Data Entry Error		30 Sep 2020 17:21:34
DataPoint Un-verified.		29 Sep 2020 16:55:17
DataPoint Verified.		29 Sep 2020 16:55:10
User opened query 'Should this be yes? Review and update as applicable.' (Site from CRA).		29 Sep 2020 16:53:41
User entered 'None (None)'	Kayla Flege (b) (4)	14 Sep 2020 20:23:37
	(b) (4)	

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:16:35

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:23:37

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:16:35

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:23:37

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:16:35

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'None (None)' reason for change: Data Entry Error	Kayla Flege (b) (4)	11 Dec 2020 15:34:04
User closed query 'Should Nasal Congestion be yes? Review and update.' (Site from CRA).	(b) (4), (b) (6)	07 Nov 2020 04:00:53
Query 'Should Nasal Congestion be yes? Review and update.' answered with 'data is correct' (Site from CRA).		30 Sep 2020 17:22:08
User entered 'Mild (Mild)' reason for change: Data Entry Error		30 Sep 2020 17:21:34
DataPoint Un-verified.		29 Sep 2020 16:55:23
DataPoint Verified.		29 Sep 2020 16:55:10
User opened query 'Should Nasal Congestion be yes? Review and update.' (Site from CRA).		29 Sep 2020 16:54:48
User entered 'None (None)'	Kayla Flege (b) (4)	14 Sep 2020 20:23:37
	(b) (4)	

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:16:35

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:23:37

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:16:35

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:23:37

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:16:35

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:23:37

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:23:37

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:16:35

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:23:37

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:16:35

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'Day 5 (Day 5)' reason for change: Data Entry Error	Kayla Flege (b) (4)	11 Dec 2020 15:33:00
User entered 'Day 3 (Day 3)'	Kayla Flege (b) (4)	14 Sep 2020 20:24:32

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:16:35

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered '30 Aug 2020'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:24:32

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:16:35

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered '0'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:24:32

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:16:35

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered '99'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:24:32

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:16:35

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User entered '%'	System	14 Sep 2020 20:24:32

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:16:35

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered '98.1' F reason for change: Data Entry Error	Kayla Flege (b) (4)	14 Sep 2020 20:25:41
User entered '98.1' C	Kayla Flege (b) (4)	14 Sep 2020 20:24:32

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:16:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:24:32

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:16:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:24:32

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:16:35

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4)	14 Sep 2020 20:24:32
	(b) (4)	

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Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:16:35

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:24:32

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:16:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:24:32

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:16:35

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:24:32

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:16:35

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:24:32

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:16:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:24:32

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:16:35

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:24:32

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:16:35

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:24:32

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Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:16:35

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:24:32

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:16:35

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:24:32

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:24:32

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:16:35

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:24:32

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:24:32

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:16:35

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:24:32

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:16:35

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'Day 6 (Day 6)' reason for change: Data Entry Error	Kayla Flege (b) (4)	11 Dec 2020 15:33:00
User entered 'Day 4 (Day 4)'	Kayla Flege (b) (4)	14 Sep 2020 20:25:41

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:16:35

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered '31 Aug 2020'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:25:41

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered '0'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:25:41

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (4)

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[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered '99'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:25:41

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:16:35

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User entered '%'	System	14 Sep 2020 20:25:41

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:16:35

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered '98.1' F	Kayla Flege (b) (4)	14 Sep 2020 20:25:41
	(b) (4)	

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:16:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4)	14 Sep 2020 20:25:41
	(b) (4)	

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:16:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:25:41

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:16:35

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:25:41

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:16:35

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:25:41

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:16:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4)	14 Sep 2020 20:25:41
	(b) (4)	

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:16:35

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:25:41

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:16:35

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:25:41

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:16:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:25:41

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:16:35

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:25:41

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:16:35

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:25:41

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:16:35

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:25:41

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:16:35

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:25:41

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:16:35

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:25:41

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:16:35

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:25:41

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:25:41

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:16:35

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:25:41

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:16:35

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'Day 7 (Day 7)' reason for change: Data Entry Error	Kayla Flege (b) (4)	11 Dec 2020 15:33:00
User entered 'Day 5 (Day 5)'	Kayla Flege (b) (4)	14 Sep 2020 20:26:46

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:16:35

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered '1 Sep 2020'	Kayla Flege (b) (4)	14 Sep 2020 20:26:46
	(b) (4)	

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:16:35

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered '0'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:26:46

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:16:35

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered '99'	Kayla Flege (b) (4)	14 Sep 2020 20:26:46
	(b) (4)	

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:16:35

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User entered '%'	System	14 Sep 2020 20:26:46

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:16:35

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered '98.1' F	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:26:46

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:16:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:26:46

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:16:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:26:46

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:16:35

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:26:46

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:16:35

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:26:46

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:16:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:26:46

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:16:35

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:26:46

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:16:35

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:26:46

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:16:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:26:46

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:16:35

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:26:46

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:16:35

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:26:46

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:16:35

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:26:46

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:16:35

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:26:46

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:16:35

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:26:46

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:16:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:26:46

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4)	14 Sep 2020 20:26:46
	(b) (4)	

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:16:35

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:26:46

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:16:35

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'Day 8 (Day 8)' reason for change: Data Entry Error	Kayla Flege (b) (4)	11 Dec 2020 15:33:00
User entered 'Day 6 (Day 6)'	Kayla Flege (b) (4)	14 Sep 2020 20:27:41

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:16:35

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered '2 Sep 2020'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:27:41

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:16:35

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered '0'	Kayla Flege (b) (4)	14 Sep 2020 20:27:41
	(b) (4)	

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:16:35

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered '99'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:27:41

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:16:35

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User entered '%'	System	14 Sep 2020 20:27:41

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:16:35

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered '98.1' F	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:27:41

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:16:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:27:41

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:16:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:27:41

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:16:35

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:27:41

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:16:35

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:27:41

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:16:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:27:41

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:16:35

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:27:41

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:16:35

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:27:41

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:16:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:27:41

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:16:35

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:27:41

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:16:35

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:27:41

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:16:35

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:27:41

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:16:35

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:27:41

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:16:35

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:27:41

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:16:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:27:41

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:27:41

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:16:35

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:27:41

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:16:35

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'Day 9 (Day 9)' reason for change: Data Entry Error	Kayla Flege (b) (4)	11 Dec 2020 15:33:00
User entered 'Day 8 (Day 8)'	Kayla Flege (b) (4)	14 Sep 2020 20:28:22

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:16:35

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered '3 Sep 2020'	Kayla Flege (b) (4)	14 Sep 2020 20:28:22
	(b) (4)	

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:16:35

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered '0'	Kayla Flege (b) (4)	14 Sep 2020 20:28:22
	(b) (4)	

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:16:35

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered '100'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:28:22

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:16:35

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User entered '%'	System	14 Sep 2020 20:28:22

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:16:35

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered '97.9' F	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:28:22

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:16:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:28:22

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:16:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:28:22

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:16:35

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:28:22

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:16:35

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:28:22

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:16:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4)	14 Sep 2020 20:28:22
	(b) (4)	

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:16:35

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:28:22

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:16:35

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4)	14 Sep 2020 20:28:22
	(b) (4)	

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:16:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:28:22

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:16:35

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:28:22

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:16:35

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:28:22

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:16:35

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:28:22

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:16:35

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:28:22

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:16:35

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:28:22

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:16:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:28:22

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:28:22

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:16:35

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:55:10
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 20:28:22

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:16:35

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'Day 2 (Day 2)'	Kayla Flege (b) (4)	11 Dec 2020 15:31:33

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:16:35

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered '27 Aug 2020'	Kayla Flege (b) (4)	11 Dec 2020 15:31:33

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:16:35

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered '0'	Kayla Flege (b) (4)	11 Dec 2020 15:31:33

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:16:35

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered missing code ND - Not Done.	Kayla Flege (b) (4)	11 Dec 2020 15:31:33

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:16:35

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User entered '%'	System	11 Dec 2020 15:31:33

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:16:35

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered missing code ND - Not Done.	Kayla Flege (b) (4)	11 Dec 2020 15:31:33

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:16:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'None (None)'	Kayla Flege (b) (4)	11 Dec 2020 15:31:33

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:16:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'None (None)'	Kayla Flege (b) (4)	11 Dec 2020 15:31:33

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:16:35

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'None (None)'	Kayla Flege (b) (4)	11 Dec 2020 15:31:33

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:16:35

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'None (None)'	Kayla Flege (b) (4)	11 Dec 2020 15:31:33

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:16:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'None (None)'	Kayla Flege (b) (4)	11 Dec 2020 15:31:33

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:16:35

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'None (None)'	Kayla Flege (b) (4)	11 Dec 2020 15:31:33

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:16:35

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'None (None)'	Kayla Flege (b) (4)	11 Dec 2020 15:31:33

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:16:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'Mild (Mild)'	Kayla Flege (b) (4)	11 Dec 2020 15:31:33

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:16:35

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'None (None)'	Kayla Flege (b) (4)	11 Dec 2020 15:31:33

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:16:35

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'None (None)'	Kayla Flege (b) (4)	11 Dec 2020 15:31:33

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:16:35

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'Mild (Mild)'	Kayla Flege (b) (4)	11 Dec 2020 15:31:33

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:16:35

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'None (None)'	Kayla Flege (b) (4)	11 Dec 2020 15:31:33

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:16:35

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'None (None)'	Kayla Flege (b) (4)	11 Dec 2020 15:31:33

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:16:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'None (None)'	Kayla Flege (b) (4)	11 Dec 2020 15:31:33

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'None (None)'	Kayla Flege (b) (4)	11 Dec 2020 15:31:33

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:16:35

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'None (None)'	Kayla Flege (b) (4)	11 Dec 2020 15:31:33

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:16:35

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'Day 3 (Day 3)'	Kayla Flege (b) (4)	11 Dec 2020 15:32:23

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:16:35

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered '28 Aug 2020'	Kayla Flege (b) (4)	11 Dec 2020 15:32:23

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:16:35

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered '0'	Kayla Flege (b) (4)	11 Dec 2020 15:32:23

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:16:35

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered missing code ND - Not Done.	Kayla Flege (b) (4)	11 Dec 2020 15:32:23

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:16:35

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User entered '%'	System	11 Dec 2020 15:32:23

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:16:35

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered missing code ND - Not Done.	Kayla Flege (b) (4)	11 Dec 2020 15:32:23

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:16:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'None (None)'	Kayla Flege (b) (4)	11 Dec 2020 15:32:23

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:16:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'None (None)'	Kayla Flege (b) (4)	11 Dec 2020 15:32:23

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:16:35

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'None (None)'	Kayla Flege (b) (4)	11 Dec 2020 15:32:23

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:16:35

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'None (None)'	Kayla Flege (b) (4)	11 Dec 2020 15:32:23

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:16:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'None (None)'	Kayla Flege (b) (4)	11 Dec 2020 15:32:23

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:16:35

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'None (None)'	Kayla Flege (b) (4)	11 Dec 2020 15:32:23

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:16:35

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'None (None)'	Kayla Flege (b) (4)	11 Dec 2020 15:32:23

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:16:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'Mild (Mild)'	Kayla Flege (b) (4)	11 Dec 2020 15:32:23

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:16:35

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'None (None)'	Kayla Flege (b) (4)	11 Dec 2020 15:32:23

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:16:35

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'None (None)'	Kayla Flege (b) (4)	11 Dec 2020 15:32:23

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:16:35

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'Mild (Mild)'	Kayla Flege (b) (4)	11 Dec 2020 15:32:23

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:16:35

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'None (None)'	Kayla Flege (b) (4)	11 Dec 2020 15:32:23

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:16:35

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'None (None)'	Kayla Flege (b) (4)	11 Dec 2020 15:32:23

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:16:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'None (None)'	Kayla Flege (b) (4)	11 Dec 2020 15:32:23

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'None (None)'	Kayla Flege (b) (4)	11 Dec 2020 15:32:23

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:16:35

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'None (None)'	Kayla Flege (b) (4)	11 Dec 2020 15:32:23

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:16:35

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: As per the CCG v 2, please add illness folder using ADD EVENT DROP Down. Please review and update the EDC as the SARS-CoV-2 serum sample dated 28 AUG 2020 is reported under Illness Visit Day 1 in PPD Central lab. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 09:32:55
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: As per the CCG v 2, please add illness folder using ADD EVENT DROP Down. Please review and update the EDC as the SARS-CoV-2 serum sample dated 28 AUG 2020 is reported under Illness Visit Day 1 in PPD Central lab. Else clarify, thank you. ' answered with 'updated' (Site from DM).	Kayla Flege (b) (4)	19 Nov 2020 22:57:46
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: As per the CCG v 2, please add illness folder using ADD EVENT DROP Down. Please review and update the EDC as the SARS-CoV-2 serum sample dated 28 AUG 2020 is reported under Illness Visit Day 1 in PPD Central lab. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 09:06:18
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: As per the CCG v 2, please add illness folder using ADD EVENT DROP Down. Please review and update the EDC as the SARS-CoV-2 serum sample dated 228 AUG 2020 is reported under Illness Visit Day 1 in PPD Central lab. Else clarify, thank you.' canceled (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 09:06:08

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Folder: Covid-19 Assessment 28 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:16:35

[Date of Visit](#)

Audit	User	Time (GMT)
User opened query ' Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: As per the CCG v 2, please add illness folder using ADD EVENT DROP Down. Please review and update the EDC as the SARS-CoV-2 serum sample dated 228 AUG 2020 is reported under Illness Visit Day 1 in PPD Central lab. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 09:05:58
User entered '28 Aug 2020'	Kayla Flege (b) (4)	14 Sep 2020 20:29:03

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:16:35

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'Yes (Y)'	Kayla Flege (b) (4)	14 Sep 2020 20:29:03

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:16:35

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User closed query 'Per CDM: Response noted yet it appears that updates are incomplete. Kindly review and reconcile with Adverse Event eCRF and update appropriately.' (Site from DM).	(b) (4), (b) (6)	08 Nov 2020 21:53:40
Query 'Per CDM: Response noted yet it appears that updates are incomplete. Kindly review and reconcile with Adverse Event eCRF and update appropriately.' answered with 'data correct' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 20:34:44
User opened query 'Per CDM: Response noted yet it appears that updates are incomplete. Kindly review and reconcile with Adverse Event eCRF and update appropriately.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 19:11:15
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	(b) (4), (b) (6)	28 Oct 2020 19:03:43
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'updated' (Site from System).	Kayla Flege (b) (4)	06 Oct 2020 21:03:13
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	06 Oct 2020 21:02:29
User entered 'Yes (Y)' reason for change: Data Entry Error	Kayla Flege (b) (4)	06 Oct 2020 21:02:29
User entered 'No (N)'	Kayla Flege (b) (4)	14 Sep 2020 20:29:03

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:16:35

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered '28 Aug 2020'	Kayla Flege (b) (4)	14 Sep 2020 20:29:03

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:16:35

Type of Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Kayla Flege (b) (4)	14 Sep 2020 20:29:03

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:16:35

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered empty.	Kayla Flege (b) (4)	14 Sep 2020 20:29:03

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:16:35

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'No (N)'	Kayla Flege (b) (4)	14 Sep 2020 20:29:03

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:16:35

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered empty.	Kayla Flege (b) (4)	14 Sep 2020 20:29:03

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:16:35

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered empty.	Kayla Flege (b) (4)	14 Sep 2020 20:29:03

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:16:35

COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:57
User entered '1'	System	06 Oct 2020 21:02:29
User entered '0'	System	14 Sep 2020 20:29:03

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:16:35

Did the subject have Respiratory Rates ≥ 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:47:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'No (N)'	(b) (4), (b) (6)	09 Nov 2020 22:43:55

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:16:35

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:47:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 22:43:55

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:16:35

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:47:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 22:43:55

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:16:35

[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:47:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 22:43:55

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:16:35

Did the subject have Heart Rate \geq 125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:47:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User closed query 'Per CDM Re-query: Please review this form and consider providing responses of either Yes or No and update accordingly.' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 09:34:51
Query 'Per CDM Re-query: Please review this form and consider providing responses of either Yes or No and update accordingly.' answered with 'updated' (Site from DM).		07 Jan 2021 23:28:21
User entered 'No (N)' reason for change: Data Entry Error		07 Jan 2021 23:28:11
User opened query 'Per CDM Re-query: Please review this form and consider providing responses of either Yes or No and update accordingly.' (Site from DM).		04 Jan 2021 15:29:35
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	10 Nov 2020 23:15:35
Query 'Data is required. Please complete.' answered with 'n/a' (Site from System).		09 Nov 2020 22:44:09
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 22:43:55
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 22:43:55

US3272260

Folder: Covid-19 Assessment 28 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:16:35

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:47:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 22:43:55

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Folder: Covid-19 Assessment 28 Aug 2020

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Generated On: 11 Aug 2021 22:16:35

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:47:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 22:43:55

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[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:47:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 22:43:55

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Did the subject have Oxygen Saturation of SpO2 \leq 93% on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:47:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Jan 2021 23:28:11
User closed query 'Data is required. Please complete.' (Site from System).		10 Nov 2020 23:15:36
Query 'Data is required. Please complete.' answered with 'n/a' (Site from System).		09 Nov 2020 22:44:21
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 22:43:55
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 22:43:55

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Generated On: 11 Aug 2021 22:16:35

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:47:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 22:43:55

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Folder: Covid-19 Assessment 28 Aug 2020

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:47:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 22:43:55

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[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:47:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 22:43:55

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Form: Covid-19 Severity Assessment

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Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:47:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Jan 2021 23:28:11
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	10 Nov 2020 23:15:38
Query 'Data is required. Please complete.' answered with 'n/a' (Site from System).	(b) (4), (b) (6)	09 Nov 2020 22:44:26
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 22:43:55
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 22:43:55

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:47:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 22:43:55

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Folder: Covid-19 Assessment 28 Aug 2020

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:47:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 22:43:55

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[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:47:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 22:43:55

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Covid-19 Severity Assessment

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Did the subject have Respiratory failure?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:47:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Jan 2021 23:28:11
User closed query 'Data is required. Please complete.' (Site from System).		10 Nov 2020 23:15:40
Query 'Data is required. Please complete.' answered with 'n/a' (Site from System).		09 Nov 2020 22:44:30
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 22:43:55
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 22:43:55

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:16:35

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:47:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 22:43:55

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:16:35

Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:47:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	10 Nov 2020 23:15:42
Query 'Data is required. Please complete.' answered with 'n/a' (Site from System).		09 Nov 2020 22:44:34
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 22:43:55
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 22:43:55

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:16:35

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:47:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 22:43:55

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:16:35

[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:47:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 22:43:55

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Folder: Covid-19 Assessment 28 Aug 2020

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Generated On: 11 Aug 2021 22:16:35

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:47:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 22:43:55

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:16:35

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:47:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 22:43:55

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:16:35

[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:47:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 22:43:55

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:16:35

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:47:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 22:43:55

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Folder: Covid-19 Assessment 28 Aug 2020

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:47:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 22:43:55

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Folder: Covid-19 Assessment 28 Aug 2020

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[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:47:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 22:43:55

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:47:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 22:43:55

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:47:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
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[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:47:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 22:43:55

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User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 22:43:55

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Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:47:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Jan 2021 23:28:11
User entered empty.		09 Nov 2020 22:43:55

US3272260

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User entered empty.	(b) (4), (b) (6)	09 Nov 2020 22:43:55

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[Evidence of Shock Requires
Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:47:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Jan 2021 23:28:11
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 22:43:55

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Audit	User	Time (GMT)
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User entered empty.	(b) (4), (b) (6)	09 Nov 2020 22:43:55

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User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 22:43:55

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[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:47:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Jan 2021 23:28:11
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 22:43:55

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:47:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 22:43:55

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[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:47:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Jan 2021 23:28:11
User entered empty.		09 Nov 2020 22:43:55

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Folder: Covid-19 Assessment 28 Aug 2020

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:47:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 22:43:55

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Folder: Covid-19 Assessment 28 Aug 2020

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[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:47:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Jan 2021 23:28:11
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 22:43:55

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:47:12
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User entered empty.	(b) (4), (b) (6)	09 Nov 2020 22:43:55

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[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:47:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Jan 2021 23:28:11
User entered empty.		09 Nov 2020 22:43:55

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Folder: Covid-19 Assessment 28 Aug 2020

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[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:47:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 22:43:55

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[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:47:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 22:43:55

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Folder: Covid-19 Assessment 28 Aug 2020

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:47:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 22:43:55

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[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:47:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Jan 2021 23:28:11
User closed query 'Data is required. Please complete.' (Site from System).		10 Nov 2020 23:15:46
Query 'Data is required. Please complete.' answered with 'n/a' (Site from System).		09 Nov 2020 22:44:40
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 22:43:55
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 22:43:55

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Folder: Covid-19 Assessment 28 Aug 2020

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Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:47:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 22:43:55

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Folder: Covid-19 Assessment 28 Aug 2020

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:47:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 22:43:55

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Folder: Covid-19 Assessment 28 Aug 2020

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:16:35

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:47:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:27:03
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 20:45:10
User entered 'No (N)' reason for change: Data Entry Error	Kayla Flege (b) (4)	14 Sep 2020 20:29:11
User entered 'Yes (Y)'	(b) (4)	
	(b) (4), (b) (6)	02 Sep 2020 14:53:30

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:16:35

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Kayla Flege (b) (4) (b) (4)	30 Oct 2020 20:12:53

US3272260

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:16:35

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:54:44
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	30 Oct 2020 20:12:53

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:16:35

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:54:47
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 31AUG2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 06:26:52
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 31AUG2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 21:26:15
User entered '31 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Nov 2020 21:26:07
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 31AUG2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 07:34:00
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 31AUG2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.	(b) (4), (b) (6)	06 Nov 2020 07:33:48
' canceled (Site from DM).		
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 31AUG2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.		06 Nov 2020 07:16:34
' (Site from DM).		
User entered '30 Aug 2020'	Kayla Flege (b) (4) (b) (4)	30 Oct 2020 20:12:53

US3272260

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:16:35

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Kayla Flege (b) (4) (b) (4)	30 Oct 2020 20:12:53

US3272260

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:16:35

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:58:57
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	30 Oct 2020 20:12:53

US3272260

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:16:35

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:58:59
User entered '1 Sep 2020'	Kayla Flege (b) (4) (b) (4)	30 Oct 2020 20:12:53

US3272260

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:16:35

[Visit](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation Requery: Saliva: Per response, since the sample is still missing in PPD. Please provide the Accession number and tracking number with shipping date in the response as the information is needed for the tracking the sample in PPD' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 12:53:09
Query 'Per GCL Lab Reconciliation Requery: Saliva: Per response, since the sample is still missing in PPD Please provide the Accession number and tracking number with shipping date in the response as the information is needed for the tracking the sample in PPD' answered with 'sample was shipped' (Site from DM).		03 Feb 2021 21:50:33
User opened query 'Per GCL Lab Reconciliation Requery: Saliva: Per response, since the sample is still missing in PPD. Please provide the Accession number and tracking number with shipping date in the response as the information is needed for the tracking the sample in PPD' (Site from DM).		22 Jan 2021 10:05:20
User closed query 'Per GCL Lab Reconciliation: Saliva: Per previous query response, since the sample is shipped. Please confirm the Accession number and tracking number with shipping date in the response for the tracking the sample in PPD as the sample is still missing in PPD.' (Site from DM).		22 Jan 2021 10:05:20
Query 'Per GCL Lab Reconciliation: Saliva: Per previous query response, since the sample is shipped Please confirm the Accession number and tracking number with shipping date in the response for the tracking the sample in PPD as the sample is still missing in PPD.' answered with 'sample shipped' (Site from DM).		13 Jan 2021 14:33:37
User opened query 'Per GCL Lab Reconciliation: Saliva: Per previous query response, since the sample is shipped. Please confirm the Accession number and tracking number with shipping date in the response for the tracking the sample in PPD as the sample is still missing in PPD.' (Site from DM).		11 Jan 2021 06:54:20

US3272260

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:16:35

[Visit](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 03SEP2020 is recorded under Illness Visit Day 7 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 09:53:34
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 03SEP2020 is recorded under Illness Visit Day 7 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'all samples had shipped.' (Site from DM).	Kayla Flege (b) (4)	11 Dec 2020 20:20:50
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 03SEP2020 is recorded under Illness Visit Day 7 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 11:02:42
User accepted default value 'Day 7 (Day 7)'	Kayla Flege (b) (4)	30 Oct 2020 20:12:53

US3272260

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:16:35

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User closed query 'please verify no specimen result for D7 in lab portal' (Site from CRA).	(b) (4), (b) (6)	18 Mar 2021 20:03:31
Query 'please verify no specimen result for D7 in lab portal' answered with 'updated' (Site from CRA).		13 Mar 2021 02:46:43
User entered 'No (N)' reason for change: Data Entry Error		13 Mar 2021 02:46:37
User opened query 'please verify no specimen result for D7 in lab portal' (Site from CRA).		23 Feb 2021 17:00:32
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	30 Oct 2020 20:12:53

US3272260

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:16:35

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	13 Mar 2021 02:46:37
User entered '3 Sep 2020'	Kayla Flege (b) (4) (b) (4)	30 Oct 2020 20:12:53

US3272260

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:16:35

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Kayla Flege (b) (4) (b) (4)	30 Oct 2020 20:12:53

US3272260

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:16:35

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:53:45
User entered 'NA (COVID-19 Negative) (NA)'	Kayla Flege (b) (4) (b) (4)	30 Oct 2020 20:12:53

US3272260

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:16:35

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:53:47
User entered empty.	Kayla Flege (b) (4) (b) (4)	30 Oct 2020 20:12:53

US3272260

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:16:35

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Kayla Flege (b) (4) (b) (4)	30 Oct 2020 20:12:53

US3272260

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:16:35

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:53:56
User entered 'NA (COVID-19 Negative) (NA)'	Kayla Flege (b) (4) (b) (4)	30 Oct 2020 20:12:53

US3272260

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:16:35

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:53:58
User entered empty.	Kayla Flege (b) (4) (b) (4)	30 Oct 2020 20:12:53

US3272260

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:16:35

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Kayla Flege (b) (4) (b) (4)	30 Oct 2020 20:12:53

US3272260

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:16:35

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:54:05
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Oct 2020 20:13:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Oct 2020 20:13:11
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Kayla Flege (b) (4)	30 Oct 2020 20:13:11
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Oct 2020 20:12:53
User entered empty.	Kayla Flege (b) (4)	30 Oct 2020 20:12:53

US3272260

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:16:35

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:54:07
User entered empty.	Kayla Flege (b) (4) (b) (4)	30 Oct 2020 20:12:53

US3272260

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:16:35

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Kayla Flege (b) (4) (b) (4)	30 Oct 2020 20:12:53

US3272260

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:16:35

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:54:13
User entered 'NA (COVID-19 Negative) (NA)'	Kayla Flege (b) (4) (b) (4)	30 Oct 2020 20:12:53

US3272260

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:16:35

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:54:15
User entered empty.	Kayla Flege (b) (4) (b) (4)	30 Oct 2020 20:12:53

US3272260

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:16:35

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:28:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Nov 2020 22:35:01

US3272260

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:28:35
User entered '28 Aug 2020'		09 Nov 2020 22:35:01

US3272260

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:28:35
User entered 'Clinic (Clinic)'		09 Nov 2020 22:35:01

US3272260

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:16:35

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD1'	System	09 Nov 2020 22:35:01

US3272260

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:28:45
User entered 'Yes (Y)'		09 Nov 2020 22:36:36

US3272260

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:35

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:28:45
User entered '28 Aug 2020'		09 Nov 2020 22:36:36

US3272260

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:28:45
User entered '08:48'		09 Nov 2020 22:36:36

US3272260

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
User entered '28 Aug 2020 08:48'	System	09 Nov 2020 22:36:36

US3272260

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:28:45
User entered '190.0' cm		09 Nov 2020 22:36:36
DataPoint set to visible.	System	09 Nov 2020 22:35:01

US3272260

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:35

Weight (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:28:45
User entered '133.3' kg		09 Nov 2020 22:36:36
DataPoint set to visible.	System	09 Nov 2020 22:35:01

US3272260

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:35

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:28:45
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	09 Nov 2020 22:40:28
User entered '36.5' C reason for change: Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 22:40:28
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	09 Nov 2020 22:36:36
User entered '36.5' (non-conformant).	(b) (4), (b) (6)	09 Nov 2020 22:36:36

US3272260

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:35

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:28:45
User entered 'Oral (Oral)'		09 Nov 2020 22:36:36

US3272260

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:35

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:28:45
User entered empty.		09 Nov 2020 22:36:36

US3272260

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:28:45
User entered '73'		09 Nov 2020 22:36:36

US3272260

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:35

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	09 Nov 2020 22:36:36

US3272260

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:28:45
User entered '12'		09 Nov 2020 22:36:36

US3272260

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	09 Nov 2020 22:36:36

US3272260

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:28:45
User entered '138'	(b) (4), (b) (6)	09 Nov 2020 22:36:36

US3272260

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	09 Nov 2020 22:36:36

US3272260

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:28:45
User entered '80'		09 Nov 2020 22:36:36

US3272260

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:35

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	09 Nov 2020 22:36:36

US3272260

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:16:35

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:28:50
User entered 'Yes (Y)'		09 Nov 2020 22:38:11

US3272260

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:16:35

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:28:50
User entered '28 Aug 2020'	(b) (4), (b) (6)	09 Nov 2020 22:38:11

US3272260

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:16:35

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:28:53
User entered 'Yes (Y)'		09 Nov 2020 22:40:44

US3272260

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:16:35

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:28:53
User entered '28 Aug 2020'	(b) (4), (b) (6)	09 Nov 2020 22:40:44

US3272260

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:16:35

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	02 Apr 2021 17:07:18
DataPoint inactivated with code reason code Data not required.		23 Feb 2021 16:52:38

US3272260

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	02 Apr 2021 17:07:18
DataPoint inactivated with code reason code Data not required.		23 Feb 2021 16:52:38

US3272260

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	02 Apr 2021 17:07:18
DataPoint inactivated with code reason code Data not required.		23 Feb 2021 16:52:38

US3272260

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:16:35

[Folder OID](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	02 Apr 2021 17:07:18
DataPoint inactivated with code reason code Data no required.		23 Feb 2021 16:52:38

US3272260

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Apr 2021 14:42:00
DataPoint inactivated with code reason code Data not required.		23 Feb 2021 16:52:48

US3272260

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Apr 2021 14:42:00
DataPoint inactivated with code reason code Data no required.		23 Feb 2021 16:52:48

US3272260

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Apr 2021 14:42:00
DataPoint inactivated with code reason code Data no required.		23 Feb 2021 16:52:48

US3272260

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Apr 2021 14:42:00
DataPoint inactivated with code reason code Data not required.		23 Feb 2021 16:52:48

US3272260

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:35

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Apr 2021 14:42:00
DataPoint inactivated with code reason code Data not required.		23 Feb 2021 16:52:48

US3272260

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:35

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Apr 2021 14:42:00
DataPoint inactivated with code reason code Data no required.		23 Feb 2021 16:52:48

US3272260

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:35

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Apr 2021 14:42:00
DataPoint inactivated with code reason code Data not required.		23 Feb 2021 16:52:48

US3272260

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Apr 2021 14:42:00
DataPoint inactivated with code reason code Data not required.		23 Feb 2021 16:52:48

US3272260

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:35

[Pulse units](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Apr 2021 14:42:00
DataPoint inactivated with code reason code Data not required.		23 Feb 2021 16:52:48

US3272260

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Apr 2021 14:42:00
DataPoint inactivated with code reason code Data no required.		23 Feb 2021 16:52:48

US3272260

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Apr 2021 14:42:00
DataPoint inactivated with code reason code Data not required.		23 Feb 2021 16:52:48

US3272260

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Apr 2021 14:42:00
DataPoint inactivated with code reason code Data not required.		23 Feb 2021 16:52:48

US3272260

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Apr 2021 14:42:00
DataPoint inactivated with code reason code Data not required.		23 Feb 2021 16:52:48

US3272260

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Apr 2021 14:42:00
DataPoint inactivated with code reason code Data no required.		23 Feb 2021 16:52:48

US3272260

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:35

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Apr 2021 14:42:00
DataPoint inactivated with code reason code Data not required.		23 Feb 2021 16:52:48

US3272260

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:35

[Height \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Apr 2021 14:42:00
DataPoint inactivated with code reason code Data not required.		23 Feb 2021 16:52:48

US3272260

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:35

[Weight \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Apr 2021 14:42:00
DataPoint inactivated with code reason code Data no required.		23 Feb 2021 16:52:48

US3272260

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:16:35

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Apr 2021 14:42:10
DataPoint inactivated with code reason code Data no required.		23 Feb 2021 16:53:00

US3272260

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:16:35

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Apr 2021 14:42:10
DataPoint inactivated with code reason code Data no required.		23 Feb 2021 16:53:00

US3272260

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:16:35

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Apr 2021 14:42:18
DataPoint inactivated with code reason code Data no required.		23 Feb 2021 16:53:09

US3272260

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:16:35

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Apr 2021 14:42:18
DataPoint inactivated with code reason code Data no required.		23 Feb 2021 16:53:09

US3272260

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

Form: Visit Date

Generated On: 11 Aug 2021 22:16:35

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'Yes (Y)'	Whitney West (b) (4)	24 Feb 2021 23:22:13

US3272260

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

Form: Visit Date

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered '09 Feb 2021'	Whitney West (b) (4)	24 Feb 2021 23:22:13

US3272260

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

Form: Visit Date

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'Home (Home)'	Whitney West (b) (4)	24 Feb 2021 23:22:13

US3272260

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

Form: Visit Date

Generated On: 11 Aug 2021 22:16:35

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:20
User entered 'UNBLND_DECIDE'	System	24 Feb 2021 23:22:13

US3272260

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

Form: Unblinding

Generated On: 11 Aug 2021 22:16:35

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered '09 Feb 2021'	Whitney West (b) (4)	24 Feb 2021 23:22:54

US3272260

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

Form: Unblinding

Generated On: 11 Aug 2021 22:16:35

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 13:38:18

US3272260

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

Form: Unblinding

Generated On: 11 Aug 2021 22:16:35

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User closed query 'Was the participant unblinded is Yes however, data is missing. Please reconcile.' (Site from System).	System	24 Feb 2021 23:23:08
Query 'Was the participant unblinded is Yes however, data is missing. Please reconcile.' answered by data change (Site from System).	System	24 Feb 2021 23:23:08
User opened query 'Was the participant unblinded is Yes however, data is missing. Please reconcile.' (Site from System).	System	24 Feb 2021 23:22:54
User entered 'Yes (Y)'	Whitney West (b) (4)	24 Feb 2021 23:22:54

US3272260

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

Form: Unblinding

Generated On: 11 Aug 2021 22:16:35

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'AMENDMENT 5 (AMENDMENT 5)' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 13:38:18

US3272260

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

Form: Unblinding

Generated On: 11 Aug 2021 22:16:35

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered '09 Feb 2021'	Whitney West (b) (4)	24 Feb 2021 23:22:54

US3272260

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

Form: Unblinding

Generated On: 11 Aug 2021 22:16:35

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User closed query 'Per CDM: Per IRT this subject was randomized to mRNA treatment assignment. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 14:40:24
Query 'Per CDM: Per IRT this subject was randomized to mRNA treatment assignment. Please review and reconcile.' answered with 'updated' (Site from DM).	Ashley Bell (b) (4)	09 Apr 2021 13:55:19
User entered 'mRNA-1273 (mRNA-1273)' reason for change: Data Entry Error	Ashley Bell (b) (4)	09 Apr 2021 13:55:12
User opened query 'Per CDM: Per IRT this subject was randomized to mRNA treatment assignment. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 10:36:16
User entered 'Placebo (Placebo)'	Whitney West (b) (4)	24 Feb 2021 23:22:54

US3272260

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

Form: Unblinding

Generated On: 11 Aug 2021 22:16:35

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User closed query 'Per CDM: Per IRT this subject was received mRNA for Day 1 Dosing. Please update data else clarify' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 14:40:26
Query 'Per CDM: Per IRT this subject was received mRNA for Day 1 Dosing. Please update data else clarify' answered with 'updated' (Site from DM).	Ashley Bell (b) (4)	09 Apr 2021 13:55:23
User entered 'mRNA-1273 (mRNA-1273)' reason for change: Data Entry Error	Ashley Bell (b) (4)	09 Apr 2021 13:55:12
User opened query 'Per CDM: Per IRT this subject was received mRNA for Day 1 Dosing. Please update data else clarify' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 16:40:47
User entered 'Placebo (Placebo)' reason for change: Data Entry Error	Whitney West (b) (4)	24 Feb 2021 23:23:36
User entered 'mRNA-1273 (mRNA-1273)'	Whitney West (b) (4)	24 Feb 2021 23:22:54

US3272260

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

Form: Unblinding

Generated On: 11 Aug 2021 22:16:35

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'Not Administered (NA)' reason for change: Data Entry Error	Ashley Bell (b) (4)	09 Apr 2021 13:55:12
User entered 'Placebo (Placebo)' reason for change: Data Entry Error	Whitney West (b) (4)	24 Feb 2021 23:23:36
User entered 'mRNA-1273 (mRNA-1273)' reason for change: Data Entry Error	Whitney West (b) (4)	24 Feb 2021 23:23:08
User entered empty.	Whitney West (b) (4)	24 Feb 2021 23:22:54

US3272260

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

Form: Unblinding

Generated On: 11 Aug 2021 22:16:35

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User closed query 'Actual dose 1 and Actual dose 2 are both recorded as mRNA-1273, however, 'Will participant receive mRNA-1273?' is Yes. Please reconcile.' (Site from System).	System	24 Feb 2021 23:23:36
Query 'Actual dose 1 and Actual dose 2 are both recorded as mRNA-1273, however, 'Will participant receive mRNA-1273?' is Yes. Please reconcile.' answered by data change (Site from System).	System	24 Feb 2021 23:23:36
User opened query 'Actual dose 1 and Actual dose 2 are both recorded as mRNA-1273, however, 'Will participant receive mRNA-1273?' is Yes. Please reconcile.' (Site from System).	System	24 Feb 2021 23:23:08
User entered 'Yes (Y)'	Whitney West (b) (4)	24 Feb 2021 23:22:54

US3272260

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

Form: Unblinding

Generated On: 11 Aug 2021 22:16:35

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:20
User entered empty.	System	09 Apr 2021 13:55:12
User entered 'I'	System	24 Feb 2021 23:23:36
User entered empty.	System	24 Feb 2021 23:22:54

US3272260

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

Form: Unblinding

Generated On: 11 Aug 2021 22:16:35

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:20
User entered '1'	System	24 Feb 2021 23:23:36
User entered empty.	System	24 Feb 2021 23:22:54

US3272260

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:16:35

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered missing code ND - Not Done; reason for change Data Entry Error	Andrea Clement (b) (4)	01 Mar 2021 17:35:59
User entered empty.	Andrea Clement (b) (4)	01 Mar 2021 17:35:20

US3272260

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:16:35

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered missing code ND - Not Done; reason for change Data Entry Error	Andrea Clement (b) (4)	01 Mar 2021 17:35:59
User entered empty.	(b) (4)	
	Andrea Clement (b) (4)	01 Mar 2021 17:35:20
	(b) (4)	

US3272260

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:16:35

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:20
User entered empty.	System	01 Mar 2021 17:35:20
DataPoint set to visible.	System	24 Feb 2021 23:23:36

US3272260

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:16:35

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered missing code ND - Not Done; reason for change Data Entry Error	Andrea Clement (b) (4)	01 Mar 2021 17:35:59
User entered empty.	Andrea Clement (b) (4)	01 Mar 2021 17:35:20

US3272260

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:16:35

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered missing code ND - Not Done; reason for change Data Entry Error	Andrea Clement (b) (4)	01 Mar 2021 17:35:59
User entered empty.	Andrea Clement (b) (4)	01 Mar 2021 17:35:20

US3272260

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:16:35

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:20
User entered empty.	System	01 Mar 2021 17:35:20
DataPoint set to visible.	System	24 Feb 2021 23:23:36

US3272260

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:35

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:20
User accepted default value 'Pre-Dose (PREDOSE)'	Andrea Clement (b) (4) (b) (4)	01 Mar 2021 17:35:20

US3272260

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'Yes (Y)'	Andrea Clement (b) (4)	01 Mar 2021 17:35:20

US3272260

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User closed query 'Date of Assessment 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	09 Apr 2021 22:05:30
User opened query 'Date of Assessment 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	31 Mar 2021 18:23:02
User entered '25 Feb 2021'	Andrea Clement (b) (4)	01 Mar 2021 17:35:20

US3272260

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User closed query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System).	System	09 Apr 2021 13:55:44
User opened query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System).	System	09 Apr 2021 13:50:39
User entered '09:46'	Andrea Clement (b) (4)	01 Mar 2021 17:35:20

US3272260

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:20
User entered '25 Feb 2021 09:46'	System	01 Mar 2021 17:35:20

US3272260

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered '36.6' C	Andrea Clement (b) (4)	01 Mar 2021 17:35:20

US3272260

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'Oral (Oral)'	Andrea Clement (b) (4)	01 Mar 2021 17:35:20

US3272260

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered empty.	Andrea Clement (b) (4)	01 Mar 2021 17:35:20

US3272260

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered '71'	Andrea Clement (b) (4)	01 Mar 2021 17:35:20

US3272260

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:20
User entered 'bpm'	System	01 Mar 2021 17:35:20

US3272260

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered '17'	Andrea Clement (b) (4)	01 Mar 2021 17:35:20

US3272260

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:20
User entered 'breaths/min'	System	01 Mar 2021 17:35:20

US3272260

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:35

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered '136'	Andrea Clement (b) (4)	01 Mar 2021 17:35:20

US3272260

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:20
User entered 'mmHg'	System	01 Mar 2021 17:35:20

US3272260

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered '84'	Andrea Clement (b) (4)	01 Mar 2021 17:35:20

US3272260

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:35

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:20
User entered 'mmHg'	System	01 Mar 2021 17:35:20

US3272260

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:16:35

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered missing code ND - Not Done; reason for change Data Entry Error	Andrea Clement (b) (4)	01 Mar 2021 17:35:59
User entered empty.	Andrea Clement (b) (4)	01 Mar 2021 17:35:20

US3272260

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:16:35

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered missing code ND - Not Done; reason for change Data Entry Error	Andrea Clement (b) (4)	01 Mar 2021 17:35:59
User entered empty.	(b) (4)	
	Andrea Clement (b) (4)	01 Mar 2021 17:35:20
	(b) (4)	

US3272260

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:16:35

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:20
User entered empty.	System	01 Mar 2021 17:35:20
DataPoint set to visible.	System	24 Feb 2021 23:23:36

US3272260

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:35

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:20
User accepted default value 'Post-Dose (POSTDOSE)'	Andrea Clement (b) (4) (b) (4)	01 Mar 2021 17:35:20

US3272260

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'Yes (Y)'	Andrea Clement (b) (4)	01 Mar 2021 17:35:20

US3272260

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User closed query 'Date of Assessment 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	09 Apr 2021 22:05:30
User opened query 'Date of Assessment 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	31 Mar 2021 18:23:02
User entered '25 Feb 2021'	Andrea Clement (b) (4)	01 Mar 2021 17:35:20

US3272260

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered '10:58'	Andrea Clement (b) (4)	01 Mar 2021 17:35:20

US3272260

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:20
User entered '25 Feb 2021 10:58'	System	01 Mar 2021 17:35:20

US3272260

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered '36.4' C	Andrea Clement (b) (4)	01 Mar 2021 17:35:20

US3272260

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'Oral (Oral)'	Andrea Clement (b) (4)	01 Mar 2021 17:35:20

US3272260

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered empty.	Andrea Clement (b) (4)	01 Mar 2021 17:35:20

US3272260

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered '72'	Andrea Clement (b) (4)	01 Mar 2021 17:35:20

US3272260

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:20
User entered 'bpm'	System	01 Mar 2021 17:35:20

US3272260

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered '17'	Andrea Clement (b) (4)	01 Mar 2021 17:35:20

US3272260

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:20
User entered 'breaths/min'	System	01 Mar 2021 17:35:20

US3272260

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered '138'	Andrea Clement (b) (4)	01 Mar 2021 17:35:20

US3272260

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:20
User entered 'mmHg'	System	01 Mar 2021 17:35:20

US3272260

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered '88'	Andrea Clement (b) (4)	01 Mar 2021 17:35:20

US3272260

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:35

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:20
User entered 'mmHg'	System	01 Mar 2021 17:35:20

US3272260

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:16:35

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'Yes (Y)'	Andrea Clement (b) (4)	01 Mar 2021 17:36:22

US3272260

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:16:35

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User closed query 'The Physical Examination Date is greater than Date of study discontinuation/completion. Please review and reconcile.' (Site from System).	System	09 Apr 2021 22:05:30
User opened query 'The Physical Examination Date is greater than Date of study discontinuation/completion. Please review and reconcile.' (Site from System).	System	09 Apr 2021 13:55:34
User entered '25 Feb 2021' reason for change: Data Entry Error	Ashley Bell (b) (4)	09 Apr 2021 13:55:34
User closed query 'The Physical Examination Date is greater than Date of study discontinuation/completion. Please review and reconcile.' (Site from System).	System	09 Apr 2021 13:51:35
User entered '09 Feb 2021' reason for change: Data Entry Error	Ashley Bell (b) (4)	09 Apr 2021 13:51:35
User opened query 'The Physical Examination Date is greater than Date of study discontinuation/completion. Please review and reconcile.' (Site from System).	System	31 Mar 2021 18:23:02
User entered '25 Feb 2021'	Andrea Clement (b) (4)	01 Mar 2021 17:36:22

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

Form: Exposure

Generated On: 11 Aug 2021 22:16:35

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'Yes (Y)'	Andrea Clement (b) (4)	01 Mar 2021 17:37:34

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

Form: Exposure

Generated On: 11 Aug 2021 22:16:35

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered empty.	Andrea Clement (b) (4)	01 Mar 2021 17:37:34

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

Form: Exposure

Generated On: 11 Aug 2021 22:16:35

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)	02 May 2021 14:23:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered empty.	Andrea Clement (b) (4)	01 Mar 2021 17:37:34

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

Form: Exposure

Generated On: 11 Aug 2021 22:16:35

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:20
User entered 'mRNA-1273'	System	01 Mar 2021 17:37:34
DataPoint set to visible.	System	24 Feb 2021 23:23:36

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

Form: Exposure

Generated On: 11 Aug 2021 22:16:35

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User closed query 'Start Date is after the Date of study discontinuation/completion on End of Study/Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	09 Apr 2021 22:05:30
User opened query 'Start Date is after the Date of study discontinuation/completion on End of Study/Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	09 Apr 2021 13:55:44
User entered '25 Feb 2021' reason for change: Data Entry Error	Ashley Bell (b) (4)	09 Apr 2021 13:55:44
User closed query 'Start Date is after the Date of study discontinuation/completion on End of Study/Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	09 Apr 2021 13:50:39
User entered '09 Feb 2021' reason for change: Data Entry Error	Ashley Bell (b) (4)	09 Apr 2021 13:50:39
User opened query 'Start Date is after the Date of study discontinuation/completion on End of Study/Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	31 Mar 2021 18:23:02
User entered '25 Feb 2021'	Andrea Clement (b) (4)	01 Mar 2021 17:37:34

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

Form: Exposure

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered '10:18'	Andrea Clement (b) (4)	01 Mar 2021 17:37:34

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

Form: Exposure

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:20
User entered '25 Feb 2021 10:18'	System	09 Apr 2021 13:55:44
User entered '09 Feb 2021 10:18'	System	09 Apr 2021 13:50:39
User entered '25 Feb 2021 10:18'	System	01 Mar 2021 17:37:34

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

Form: Exposure

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'Left Arm (LEFT ARM)'	Andrea Clement (b) (4)	01 Mar 2021 17:37:34

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

Form: Exposure

Generated On: 11 Aug 2021 22:16:35

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:20
User entered 'ONCE'	System	01 Mar 2021 17:37:34

US3272260

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

Form: Exposure

Generated On: 11 Aug 2021 22:16:35

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:20
User entered 'INTRAMUSCULAR'	System	01 Mar 2021 17:37:34

US3272260

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:16:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'Yes (Y)'	Andrea Clement (b) (4)	01 Mar 2021 17:39:43

US3272260

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:16:35

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered '9 Feb 2021'	Andrea Clement (b) (4)	01 Mar 2021 17:39:43

US3272260

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered '17:08'	Andrea Clement (b) (4)	01 Mar 2021 17:39:43

US3272260

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:20
User entered '9 Feb 2021 17:08'	System	01 Mar 2021 17:39:43

US3272260

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:16:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Mar 2021 17:40:14
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Mar 2021 17:40:14
User entered 'Yes (Y)' reason for change: Data Entry Error	Andrea Clement (b) (4)	01 Mar 2021 17:40:14
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Mar 2021 17:32:09
User entered empty.	Andrea Clement (b) (4)	01 Mar 2021 17:32:09

US3272260

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:16:35

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User closed query 'Per GCL Lab Reconciliation: Central Nasopharyngeal Swab (Single): Sample dated 25-Feb-2021 is recorded under OL-D1 (1) visit in EDC, however the same is reported with date 09-Feb-2021 (Accession No : 1F606642263 per Preclarus) in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else clarify, Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 07:01:45
Query 'Per GCL Lab Reconciliation: Central Nasopharyngeal Swab (Single): Sample dated 25-Feb-2021 is recorded under OL-D1 (1) visit in EDC, however the same is reported with date 09-Feb-2021 (Accession No : 1F606642263 per Preclarus) in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else clarify, Thank you.' answered with 'sample is from 09Feb2021' (Site from DM).	Ashley Bell (b) (4)	19 Apr 2021 18:47:56
User entered '09 Feb 2021' reason for change: Data Entry Error	Ashley Bell (b) (4)	19 Apr 2021 18:47:37
User opened query 'Per GCL Lab Reconciliation: Central Nasopharyngeal Swab (Single): Sample dated 25-Feb-2021 is recorded under OL-D1 (1) visit in EDC, however the same is reported with date 09-Feb-2021 (Accession No : 1F606642263 per Preclarus) in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else clarify, Thank you.' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 08:40:35
User closed query 'Collection 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	09 Apr 2021 22:05:30
User opened query 'Collection 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	09 Apr 2021 13:56:00

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EAB) (1725)

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:16:35

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '25 Feb 2021' reason for change: Data Entry Error	Ashley Bell (b) (4)	09 Apr 2021 13:56:00
User entered '9 Feb 2021' reason for change: Data Entry Error	Andrea Clement (b) (4)	01 Mar 2021 17:40:14
User entered empty.	Andrea Clement (b) (4)	01 Mar 2021 17:32:09

US3272260

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:16:35

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered '17:20' reason for change: Data Entry Error	Andrea Clement (b) (4)	01 Mar 2021 17:40:14
User entered empty.	Andrea Clement (b) (4)	01 Mar 2021 17:32:09

US3272260

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:20
User entered '09 Feb 2021 17:20'	System	19 Apr 2021 18:47:37
User entered '25 Feb 2021 17:20'	System	09 Apr 2021 13:56:00
User entered '9 Feb 2021 17:20'	System	01 Mar 2021 17:40:14
User entered empty.	System	01 Mar 2021 17:32:09

US3272260

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

Form: Continuing

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'Yes (Y)'	Andrea Clement (b) (4)	01 Mar 2021 17:40:20

US3272260

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

Form: Continuing

Generated On: 11 Aug 2021 22:16:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:20
User entered 'I'	System	01 Mar 2021 17:40:20

US3272260

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Mar 2021 14:58:40

US3272260

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:35

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
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	09 Apr 2021 22:05:30
User closed query 'OL Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	09 Apr 2021 13:55:44
Query 'OL Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	09 Apr 2021 13:55:44
User opened query 'OL Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	09 Apr 2021 13:50:39
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	31 Mar 2021 18:23:02
User entered '04 Mar 2021'	(b) (4), (b) (6)	09 Mar 2021 14:58:40

US3272260

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	09 Mar 2021 14:58:40

US3272260

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:16:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
User entered empty.	(b) (4), (b) (6)	09 Mar 2021 14:58:40

US3272260

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:24:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Mar 2021 14:58:44

US3272260

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:16:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:59
User entered 'I'	System	09 Mar 2021 14:58:44

US3272260

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:16:35

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:39:59
User entered '1'	System	09 Mar 2021 14:58:44
DataPoint set to visible.	System	09 Mar 2021 14:58:44

US3272260

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:16:35

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Mar 2021 21:09:09

US3272260

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:16:35

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User closed query 'Visit Date is after Date of study discontinuation/completion. Please reconcile.' (Site from System).	System	09 Apr 2021 22:05:30
User opened query 'Visit Date is after Date of study discontinuation/completion. Please reconcile.' (Site from System).	System	31 Mar 2021 18:23:02
User closed query 'OL-D29 Visit Date is < 25 days or > 42 days after the Participant Decision visit vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	30 Mar 2021 09:46:20
Query 'OL-D29 Visit Date is < 25 days or > 42 days after the Participant Decision visit vaccination. Please reconcile or confirm dates.' answered with 'data entered is correct' (Site from System).	(b) (4), (b) (6)	29 Mar 2021 21:09:24
User opened query 'OL-D29 Visit Date is < 25 days or > 42 days after the Participant Decision visit vaccination. Please reconcile or confirm dates.' (Site from System).	System	29 Mar 2021 21:09:09
User entered '17 Mar 2021'	(b) (4), (b) (6)	29 Mar 2021 21:09:09

US3272260

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	29 Mar 2021 21:09:09

US3272260

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:16:35

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:55
User entered 'OLD29'	System	29 Mar 2021 21:09:09

US3272260

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'No (N)'	Ashley Bell (b) (4)	09 Apr 2021 22:06:18

US3272260

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered empty.	Ashley Bell (b) (4)	09 Apr 2021 22:06:18

US3272260

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered empty.	Ashley Bell (b) (4)	09 Apr 2021 22:06:18

US3272260

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:55
User entered empty.	System	09 Apr 2021 22:06:18

US3272260

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered empty.	Ashley Bell (b) (4)	09 Apr 2021 22:06:18

US3272260

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered empty.	Ashley Bell (b) (4)	09 Apr 2021 22:06:18

US3272260

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered empty.	Ashley Bell (b) (4)	09 Apr 2021 22:06:18

US3272260

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered empty.	Ashley Bell (b) (4)	09 Apr 2021 22:06:18

US3272260

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:55
User entered empty.	System	09 Apr 2021 22:06:18

US3272260

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered empty.	Ashley Bell (b) (4)	09 Apr 2021 22:06:18

US3272260

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:55
User entered empty.	System	09 Apr 2021 22:06:18

US3272260

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered empty.	Ashley Bell (b) (4)	09 Apr 2021 22:06:18

US3272260

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:55
User entered empty.	System	09 Apr 2021 22:06:18

US3272260

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered empty.	Ashley Bell (b) (4)	09 Apr 2021 22:06:18

US3272260

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:35

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:55
User entered empty.	System	09 Apr 2021 22:06:18

US3272260

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:35

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:55

US3272260

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:16:35

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:55

US3272260

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:35

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:55
User accepted default value 'Pre-Dose (PREDOSE)'		29 Mar 2021 21:10:08

US3272260

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Mar 2021 21:10:08

US3272260

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User closed query 'Date of Assessment 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	09 Apr 2021 22:05:30
User opened query 'Date of Assessment 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	31 Mar 2021 18:23:02
User entered '17 Mar 2021'	(b) (4), (b) (6)	29 Mar 2021 21:10:08

US3272260

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered '10:58'	(b) (4), (b) (6)	29 Mar 2021 21:10:08

US3272260

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:55
User entered '17 Mar 2021 10:58'	System	29 Mar 2021 21:10:08

US3272260

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered '36.5' C	(b) (4), (b) (6)	29 Mar 2021 21:10:08

US3272260

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'Oral (Oral)'	(b) (4), (b) (6)	29 Mar 2021 21:10:08

US3272260

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 21:10:08

US3272260

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered '72'	(b) (4), (b) (6)	29 Mar 2021 21:10:08

US3272260

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:55
User entered 'bpm'	System	29 Mar 2021 21:10:08

US3272260

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered '17'	(b) (4), (b) (6)	29 Mar 2021 21:10:08

US3272260

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:55
User entered 'breaths/min'	System	29 Mar 2021 21:10:08

US3272260

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered '137'	(b) (4), (b) (6)	29 Mar 2021 21:10:08

US3272260

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:55
User entered 'mmHg'	System	29 Mar 2021 21:10:08

US3272260

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered '82'	(b) (4), (b) (6)	29 Mar 2021 21:10:08

US3272260

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:16:35

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:55
User entered 'mmHg'	System	29 Mar 2021 21:10:08

US3272260

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:35

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:55
User accepted default value 'Post-Dose (POSTDOSE)'		29 Mar 2021 21:16:01

US3272260

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'No (N)'	(b) (4), (b) (6)	29 Mar 2021 21:16:01

US3272260

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 21:16:01

US3272260

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 21:16:01

US3272260

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:55
User entered empty.	System	29 Mar 2021 21:16:01

US3272260

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 21:16:01

US3272260

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 21:16:01

US3272260

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 21:16:01

US3272260

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 21:16:01

US3272260

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:55
User entered empty.	System	29 Mar 2021 21:16:01

US3272260

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 21:16:01

US3272260

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:55
User entered empty.	System	29 Mar 2021 21:16:01

US3272260

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 21:16:01

US3272260

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:55
User entered empty.	System	29 Mar 2021 21:16:01

US3272260

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 21:16:01

US3272260

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:16:35

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:55
User entered empty.	System	29 Mar 2021 21:16:01

US3272260

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:16:35

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Mar 2021 21:16:21

US3272260

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:16:35

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User closed query 'The Physical Examination Date is greater than Date of study discontinuation/completion. Please review and reconcile.' (Site from System).	System	09 Apr 2021 22:05:30
User opened query 'The Physical Examination Date is greater than Date of study discontinuation/completion. Please review and reconcile.' (Site from System).	System	31 Mar 2021 18:23:02
User entered '17 Mar 2021'	(b) (4), (b) (6)	29 Mar 2021 21:16:21

US3272260

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:16:35

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'No (N)'	(b) (4), (b) (6)	29 Mar 2021 21:16:28

US3272260

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:16:35

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
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).		29 Mar 2021 21:17:22
User entered 'Other (OTHER)' reason for change:	(b) (4), (b) (6)	29 Mar 2021 21:17:22
Data Entry Error		
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	29 Mar 2021 21:16:28
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 21:16:28

US3272260

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:16:35

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)	02 May 2021 14:43:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'Subject received 1 dose in initial round of vaccination.' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Mar 2021 21:17:22
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 21:16:28

US3272260

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:16:35

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:55
DataPoint set to visible.	System	09 Apr 2021 13:55:12
User entered empty.	System	29 Mar 2021 21:16:28
DataPoint set to invisible.	System	09 Mar 2021 14:58:44

US3272260

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:16:35

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 21:16:28

US3272260

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 21:16:28

US3272260

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:55
User entered empty.	System	29 Mar 2021 21:16:28

US3272260

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 21:16:28

US3272260

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:55
User entered empty.	System	29 Mar 2021 21:16:28

US3272260

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:16:35

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:55
User entered empty.	System	29 Mar 2021 21:16:28

US3272260

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:16:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'Yes (Y)'	Ashley Bell (b) (4)	09 Apr 2021 22:06:33

US3272260

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:16:35

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered '17 Mar 2021'	Ashley Bell (b) (4)	09 Apr 2021 22:06:33

US3272260

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:16:35

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered '11:00'	Ashley Bell (b) (4)	09 Apr 2021 22:06:33

US3272260

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:55
User entered '17 Mar 2021 11:00'	System	09 Apr 2021 22:06:33

US3272260

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Apr 2021 19:17:26
User entered 'Yes (Y)'		29 Mar 2021 21:17:26

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Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:16:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:55
User entered empty.	System	06 Apr 2021 19:17:26
User entered '1'	System	29 Mar 2021 21:17:26

US3272260

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:16:35

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:09:53
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
User closed query 'Please add AE of COVID-19 as illness result was positive' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 04:04:53
Query 'Please add AE of COVID-19 as illness result was positive' answered with 'updated' (Site from CRA).	Kayla Flege (b) (4)	19 Nov 2020 22:56:19
User opened query 'Please add AE of COVID-19 as illness result was positive' (Site from CRA).	(b) (4), (b) (6)	07 Nov 2020 16:27:18
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 16:56:11
User entered 'Yes (Y)' reason for change: Data Entry Error	Kayla Flege (b) (4)	11 Sep 2020 14:31:56
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 15:05:34

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:16:35

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:00:43

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:16:35

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:00:43
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:20:05
User closed query 'Consider adding to the covid symptoms log.' (Site from CRA).	(b) (4), (b) (6)	07 Nov 2020 16:28:08
Query 'Consider adding to the covid symptoms log.' answered with 'ok' (Site from CRA).	Kayla Flege (b) (4)	02 Oct 2020 20:01:56
User opened query 'Consider adding to the covid symptoms log.' (Site from CRA).	(b) (4), (b) (6)	29 Sep 2020 16:57:36
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Upper respiratory tract disorders (excl infections), HLT: Nasal congestion and inflammations, PT: Nasal congestion, LLT: Nasal congestion - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 14:36:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 14:36:47
Data point term sent to Coder	System	11 Sep 2020 14:35:02
User entered 'Nasal Congestion'	Kayla Flege (b) (4)	11 Sep 2020 14:34:48

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:16:35

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:00:43
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:20:05
User entered 'No (N)'	Kayla Flege (b) (4)	11 Sep 2020 14:34:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:16:35

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:00:43
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:20:05
User entered 'No (N)'	Kayla Flege (b) (4)	11 Sep 2020 14:34:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:16:35

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:00:43
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:20:05
User entered 'No (N)'	Kayla Flege (b) (4)	11 Sep 2020 14:34:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:00:43
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:20:05
User entered '26 Aug 2020'	Kayla Flege (b) (4)	11 Sep 2020 14:34:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:00:43
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:20:05
User entered empty.	Kayla Flege (b) (4)	11 Sep 2020 14:34:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:16:35

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:00:43
User entered empty.	System	11 Sep 2020 14:34:48

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:16:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:00:43
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:20:05
User entered 'No (N)'	Kayla Flege (b) (4)	11 Sep 2020 14:34:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:16:35

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:00:43
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:20:05
User entered '29 Aug 2020'	Kayla Flege (b) (4)	11 Sep 2020 14:34:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:00:43
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:20:05
User entered empty.	Kayla Flege (b) (4)	11 Sep 2020 14:34:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:16:35

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:00:43
User entered empty.	System	11 Sep 2020 14:34:48

US3272260

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:16:35

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:00:43
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:20:05
User entered 'Grade 1/Mild (Grade 1/Mild)'	Kayla Flege (b) (4)	11 Sep 2020 14:34:48
	(b) (4)	

US3272260

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:16:35

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:00:43
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:20:05
User closed query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	11 Sep 2020 14:35:50
User opened query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	11 Sep 2020 14:35:39
User entered 'No (N)' reason for change: Data Entry Error	Kayla Flege (b) (4)	11 Sep 2020 14:35:39
User closed query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	(b) (4)	11 Sep 2020 14:35:04
User entered 'Yes (Y)' reason for change: Data Entry Error	Kayla Flege (b) (4)	11 Sep 2020 14:35:04
User opened query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	11 Sep 2020 14:34:48
User entered 'No (N)'	Kayla Flege (b) (4)	11 Sep 2020 14:34:48

US3272260

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:16:35

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:00:43
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:20:05
User entered '0' reason for change: Data Entry Error	Kayla Flege (b) (4)	11 Sep 2020 14:35:50
User entered '1'	Kayla Flege (b) (4)	11 Sep 2020 14:34:48

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:16:35

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:00:43
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:20:05
User entered '0'	Kayla Flege (b) (4)	11 Sep 2020 14:34:48
	(b) (4)	

US3272260

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:16:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:00:43
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:20:05
User entered '0'	Kayla Flege (b) (4)	11 Sep 2020 14:34:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:16:35

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:00:43
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:20:05
User entered empty.	Kayla Flege (b) (4)	11 Sep 2020 14:34:48
	(b) (4)	

US3272260

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:16:35

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:00:43
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:20:05
User entered empty.	Kayla Flege (b) (4)	11 Sep 2020 14:34:48
	(b) (4)	

US3272260

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:16:35

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:00:43
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:20:05
User entered empty.	Kayla Flege (b) (4)	11 Sep 2020 14:34:48
	(b) (4)	

US3272260

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:16:35

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:00:43
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:20:05
User entered empty.	Kayla Flege (b) (4)	11 Sep 2020 14:34:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:16:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:00:43
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:20:05
User entered '0'	Kayla Flege (b) (4)	11 Sep 2020 14:34:48
	(b) (4)	

US3272260

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:16:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:00:43
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:20:05
User entered '0'	Kayla Flege (b) (4)	11 Sep 2020 14:34:48
	(b) (4)	

US3272260

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:16:35

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:00:43
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:20:05
User entered '0'	Kayla Flege (b) (4)	11 Sep 2020 14:34:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:16:35

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:00:43
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:20:05
User entered 'Not Related (NOT RELATED)'	Kayla Flege (b) (4) (b) (4)	11 Sep 2020 14:34:48

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:16:35

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:00:43
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:20:05
User entered 'Not Related (NOT RELATED)'	Kayla Flege (b) (4) (b) (4)	11 Sep 2020 14:34:48

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:16:35

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:00:43
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:20:05
User entered 'None (NONE)'	Kayla Flege (b) (4)	11 Sep 2020 14:34:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:16:35

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:00:43
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:20:05
User entered 'l'	Kayla Flege (b) (4)	11 Sep 2020 14:34:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:16:35

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:00:43
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:20:05
User entered '0'	Kayla Flege (b) (4)	11 Sep 2020 14:34:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:16:35

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:00:43
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:20:05
User entered '0'	Kayla Flege (b) (4)	11 Sep 2020 14:34:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:16:35

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:00:43
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:20:05
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Kayla Flege (b) (4) (b) (4)	11 Sep 2020 14:34:48

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:16:35

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:00:43
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:20:05
User entered empty.	Kayla Flege (b) (4)	11 Sep 2020 14:34:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:16:35

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:00:43
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:20:05
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	11 Sep 2020 14:35:39
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	11 Sep 2020 14:35:39
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	11 Sep 2020 14:35:04
User entered empty.	Kayla Flege (b) (4) (b) (4)	11 Sep 2020 14:34:48

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:16:35

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:00:43
User entered '0'	System	11 Sep 2020 14:35:39
User entered '1'	System	11 Sep 2020 14:35:04
User entered '0'	System	11 Sep 2020 14:34:48

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:16:35

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:00:43
User entered '0'	System	11 Sep 2020 14:34:48

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:16:35

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:00:43

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:16:35

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 01:54:32
User entered 'USA-US070-2020-mRNA-1273-P301000023'	System	21 Nov 2020 01:54:27
User entered 'New'	(b) (4), (b) (6)	21 Nov 2020 01:54:27
DataPoint activated with code reason code Data required.	Kayla Flege (b) (4)	19 Nov 2020 22:48:09
DataPoint inactivated with code reason code Data not required.	Kayla Flege (b) (4)	19 Nov 2020 22:47:11

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:16:35

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User closed query 'Per CDM, per Sponsor Review: Please update AE term to Symptomatic Covid-19 since 'Is this event a confirmed diagnosis of Symptomatic Covid-19?' = Yes.' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 11:03:46
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4)	19 Apr 2021 18:42:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Apr 2021 18:42:45
Query 'Per CDM, per Sponsor Review: Please update AE term to Symptomatic Covid-19 since 'Is this event a confirmed diagnosis of Symptomatic Covid-19?' = Yes.' answered with 'updated' (Site from DM).	Ashley Bell (b) (4)	19 Apr 2021 18:42:37
Data point term sent to Coder	System	19 Apr 2021 18:41:43
DataPoint Un-verified.	Ashley Bell (b) (4)	19 Apr 2021 18:41:30
Coding entries removed.	Ashley Bell (b) (4)	19 Apr 2021 18:41:30
Signature has been broken.	Ashley Bell (b) (4)	19 Apr 2021 18:41:30
User entered 'Symptomatic COVID 19' reason for change: Data Entry Error	Ashley Bell (b) (4)	19 Apr 2021 18:41:30
User opened query 'Per CDM, per Sponsor Review: Please update AE term to Symptomatic Covid-19 since 'Is this event a confirmed diagnosis of Symptomatic Covid-19?' = Yes.' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 16:26:04
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:20:05
User closed query 'Per CDM: please inactivate this line if confirmed line is not needed.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 01:04:42
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4)	19 Nov 2020 22:52:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Nov 2020 22:52:53
Data point term sent to Coder	System	19 Nov 2020 22:51:56

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:16:35

[Adverse event](#)

Audit	User	Time (GMT)
User entered 'COVID 19' reason for change: Data Entry Error	Kayla Flege (b) (4)	19 Nov 2020 22:51:18
Data point term sent to Coder	System	19 Nov 2020 22:48:52
DataPoint activated with code reason code Data required.	Kayla Flege (b) (4)	19 Nov 2020 22:48:09
Data point term sent to Coder	System	19 Nov 2020 22:47:49
DataPoint inactivated with code reason code Data not required.	Kayla Flege (b) (4)	19 Nov 2020 22:47:11
Query 'Per CDM: please inactivate this line if confirmed line is not needed.' answered with 'updated' (Site from DM).	Kayla Flege (b) (4)	19 Nov 2020 22:46:51
User opened query 'Per CDM: please inactivate this line if confirmed line is not needed.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 19:23:16
User closed query 'Data is required. Please complete.' (Site from System).		11 Nov 2020 01:57:47
User closed query 'Per DM CLR - RQ: Site's response noted. However, taking medication is not one of the criteria for Solicited Adverse Event AE reporting criteria per Protocol section 8.3.4. Please review and update to delete/remove AE as applicable Otherwise, clarify. ' (Site from DM).		11 Nov 2020 01:57:45
Query 'Data is required. Please complete.' answered with 'UPDATED' (Site from System).		09 Nov 2020 22:12:24
Query 'Per DM CLR - RQ: Site's response noted. However, taking medication is not one of the criteria for Solicited Adverse Event AE reporting criteria per Protocol section 8.3.4. Please review and update to delete/remove AE as applicable. Otherwise, clarify. ' answered with 'UPDATED' (Site from DM).		09 Nov 2020 22:12:21
Data point term sent to Coder	System	09 Nov 2020 22:12:12
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 22:12:08
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 22:12:08
User closed query 'Since illness visit was conducted, consider adding to the covid symptoms log.' (Site from CRA).		07 Nov 2020 16:28:44

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:16:35

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR - RQ: Site's response noted. However, taking medication is not one of the criteria for Solicited Adverse Event AE reporting criteria per Protocol section 8.3.4. Please review and update to delete/remove AE as applicable Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 08:27:10
User closed query 'Per DM CLR: Please note that solicited reactions are only to reported as AE if this meets AE reporting criteria per protocol. Please review if recorded event meets criteria. Else, consider deleting event as this has been captured in Diary Data. Otherwise provide clarification. ' (Site from DM).		28 Oct 2020 18:53:59
Query 'Per DM CLR: Please note that solicited reactions are only to reported as AE if this meets AE reporting criteria per protocol. Please review if recorded event meets criteria. Else, consider deleting event as this has been captured in Diary Data. Otherwise provide clarification. ' answered with 'pt took medication ' (Site from DM).	Kayla Flege (b) (4)	20 Oct 2020 23:00:21
User opened query 'Per DM CLR: Please note that solicited reactions are only to reported as AE if this meets AE reporting criteria per protocol. Please review if recorded event meets criteria. Else, consider deleting event as this has been captured in Diary Data. Otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 23:16:23
Query 'Since illness visit was conducted, consider adding to the covid symptoms log.' answered with 'ok' (Site from CRA).	Kayla Flege (b) (4)	02 Oct 2020 20:02:04
User opened query 'Since illness visit was conducted, consider adding to the covid symptoms log.' (Site from CRA).	(b) (4), (b) (6)	29 Sep 2020 16:58:49
User coded data point as SOC: Nervous system disorders, HLT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 14:37:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 14:37:40
Data point term sent to Coder	System	11 Sep 2020 14:37:06

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

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[Adverse event](#)

Audit	User	Time (GMT)
User entered 'Headache'	Kayla Flege (b) (4) (b) (4)	11 Sep 2020 14:36:34

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:16:35

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:20:05
User entered 'Yes (Y)' reason for change: Data Entry Error	Kayla Flege (b) (4)	19 Nov 2020 22:51:18
DataPoint activated with code reason code Data required.	Kayla Flege (b) (4)	19 Nov 2020 22:48:09
DataPoint inactivated with code reason code Data not required.	Kayla Flege (b) (4)	19 Nov 2020 22:47:11
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 01:57:48
Query 'Data is required. Please complete.' answered with 'UPDATED' (Site from System).		09 Nov 2020 22:12:27
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 22:12:08
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 22:12:08
User entered 'No (N)'	Kayla Flege (b) (4)	11 Sep 2020 14:36:34

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:16:35

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:20:05
User entered 'No (N)' reason for change: Data Entry Error	Kayla Flege (b) (4)	19 Nov 2020 22:51:18
DataPoint activated with code reason code Data required.	Kayla Flege (b) (4)	19 Nov 2020 22:48:09
DataPoint inactivated with code reason code Data not required.	Kayla Flege (b) (4)	19 Nov 2020 22:47:11
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 01:57:50
Query 'Data is required. Please complete.' answered with 'UPDATED' (Site from System).		09 Nov 2020 22:12:30
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 22:12:08
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 22:12:08
User entered 'No (N)'	Kayla Flege (b) (4)	11 Sep 2020 14:36:34

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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)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:20:05
User entered 'Yes (Y)' reason for change: Data Entry Error	Kayla Flege (b) (4)	19 Nov 2020 22:51:18
DataPoint activated with code reason code Data required.	Kayla Flege (b) (4)	19 Nov 2020 22:48:09
DataPoint inactivated with code reason code Data not required.	Kayla Flege (b) (4)	19 Nov 2020 22:47:11
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 01:57:51
Query 'Data is required. Please complete.' answered with 'UPDATED' (Site from System).		09 Nov 2020 22:12:32
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 22:12:08
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 22:12:08
User entered 'No (N)'	Kayla Flege (b) (4)	11 Sep 2020 14:36:34

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:16:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
User closed query 'PV Query: Please clarify date of day 1 of symptom log. Day 1 states 26 Aug 2020 and day 2 states 29 Aug 2020.' (Site from Safety).	(b) (4), (b) (6)	11 Dec 2020 21:14:11
Query 'PV Query: Please clarify date of day 1 of symptom log. Day 1 states 26 Aug 2020 and day 2 states 29 Aug 2020.' answered with 'updated' (Site from Safety).	Kayla Flege (b) (4) (b) (4)	11 Dec 2020 15:33:13
User opened query 'PV Query: Please clarify date of day 1 of symptom log. Day 1 states 26 Aug 2020 and day 2 states 29 Aug 2020.' (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 18:03:21
User closed query 'PV Query: Please clarify onset date for the event as first symptoms occurred on 26 Aug 2020 per symptom log. Please update onset date or symptom log accordingly' (Site from Safety).	(b) (4), (b) (6)	03 Dec 2020 17:54:15
Query 'PV Query: Please clarify onset date for the event as first symptoms occurred on 26 Aug 2020 per symptom log. Please update onset date or symptom log accordingly' answered with 'updated' (Site from Safety).	Kayla Flege (b) (4) (b) (4)	01 Dec 2020 18:23:41
DataPoint Un-verified.	Kayla Flege (b) (4) (b) (4)	01 Dec 2020 18:23:36
User entered '26 Aug 2020' reason for change: Data Entry Error	Kayla Flege (b) (4) (b) (4)	01 Dec 2020 18:23:36
Query 'Per CDM: As per CCG, Start time is required for an AE that starts within 24 hours of dosing. Please review & update accordingly, else clarify.' canceled (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 22:30:43
User opened query 'PV Query: Please clarify onset date for the event as first symptoms occurred on 26 Aug 2020 per symptom log. Please update onset date or symptom log accordingly' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 21:33:02
User opened query 'Per CDM: As per CCG, Start time is required for an AE that starts within 24 hours of dosing. Please review & update accordingly, else clarify.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 14:14:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:20:05
User entered '22 Aug 2020' reason for change: Data Entry Error	Kayla Flege (b) (4) (b) (4)	19 Nov 2020 22:51:18

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:16:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Kayla Flege (b) (4)	19 Nov 2020 22:48:09
DataPoint inactivated with code reason code Data not required.	Kayla Flege (b) (4)	19 Nov 2020 22:47:11
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 01:57:53
Query 'Data is required. Please complete.' answered with 'UPDATED' (Site from System).		09 Nov 2020 22:12:36
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 22:12:08
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 22:12:08
User closed query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom HEADACHE on 25 AUG 2020. Please review if this should be reconciled. Else, provide clarification on dates.' (Site from DM).		28 Oct 2020 18:53:57
Query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom HEADACHE on 25 AUG 2020. Please review if this should be reconciled. Else, provide clarification on dates.' answered with 'Updated' (Site from DM).	Kayla Flege (b) (4)	20 Oct 2020 23:00:07
User entered '25 Aug 2020' reason for change: Data Entry Error	Kayla Flege (b) (4)	20 Oct 2020 23:00:01
User opened query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom HEADACHE on 25 AUG 2020. Please review if this should be reconciled. Else, provide clarification on dates.' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 23:16:38
User entered '26 Aug 2020'	Kayla Flege (b) (4)	11 Sep 2020 14:36:34

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:16:35

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
User closed query 'Data is required. Please provide.' (Site from System).	System	01 Dec 2020 18:23:36
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	24 Nov 2020 14:08:38
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:20:05
Query 'Data is required. Please provide.' answered with 'unknown' (Site from System).	Kayla Flege (b) (4)	19 Nov 2020 22:52:02
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Nov 2020 22:51:18
DataPoint activated with code reason code Data required.	Kayla Flege (b) (4)	19 Nov 2020 22:48:09
DataPoint inactivated with code reason code Data not required.	Kayla Flege (b) (4)	19 Nov 2020 22:47:11
User entered empty.	Kayla Flege (b) (4)	11 Sep 2020 14:36:34

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:16:35

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Kayla Flege (b) (4)	19 Nov 2020 22:48:09
DataPoint inactivated with code reason code Data not required.	Kayla Flege (b) (4)	19 Nov 2020 22:47:11
User entered empty.	System	11 Sep 2020 14:36:34

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:16:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Un-verified.	Kayla Flege (b) (4)	01 Dec 2020 18:23:36
User entered 'No (N)' reason for change: Data Entry Error	Kayla Flege (b) (4)	01 Dec 2020 18:23:36
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:20:05
User entered 'Yes (Y)' reason for change: Data Entry Error	Kayla Flege (b) (4)	19 Nov 2020 22:51:18
DataPoint activated with code reason code Data required.	Kayla Flege (b) (4)	19 Nov 2020 22:48:09
DataPoint inactivated with code reason code Data not required.	Kayla Flege (b) (4)	19 Nov 2020 22:47:11
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 01:57:55
Query 'Data is required. Please complete.' answered with 'UPDATED' (Site from System).		09 Nov 2020 22:12:39
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 22:12:08
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 22:12:08
User entered 'No (N)'	Kayla Flege (b) (4)	11 Sep 2020 14:36:34

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:16:35

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
User closed query 'PV Query: Please confirm the end date, since the subject still had symptoms on 29-AUG-2020.' (Site from Safety).	(b) (4), (b) (6)	11 Dec 2020 21:14:25
Query 'PV Query: Please confirm the end date, since the subject still had symptoms on 29-AUG-2020.' answered with 'updated symptom log' (Site from Safety).	Kayla Flege (b) (4) (b) (4)	11 Dec 2020 15:35:47
User opened query 'PV Query: Please confirm the end date, since the subject still had symptoms on 29-AUG-2020.' (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 18:03:46
User closed 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)	03 Dec 2020 17:54:19
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.' answered with 'updated' (Site from Safety).	Kayla Flege (b) (4) (b) (4)	01 Dec 2020 18:23:45
DataPoint Un-verified.	Kayla Flege (b) (4) (b) (4)	01 Dec 2020 18:23:36
User entered '29 Aug 2020' reason for change: Data Entry Error	Kayla Flege (b) (4) (b) (4)	01 Dec 2020 18:23:36
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)	24 Nov 2020 21:32:02
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:20:05
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	19 Nov 2020 22:54:47
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	19 Nov 2020 22:54:47
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	19 Nov 2020 22:54:33

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:16:35

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Kayla Flege (b) (4)	19 Nov 2020 22:48:09
DataPoint inactivated with code reason code Data not required.	Kayla Flege (b) (4)	19 Nov 2020 22:47:11
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 22:12:08
User entered '29 Aug 2020'	Kayla Flege (b) (4)	11 Sep 2020 14:36:34

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:16:35

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

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:20:05
DataPoint activated with code reason code Data required.	Kayla Flege (b) (4)	19 Nov 2020 22:48:09
DataPoint inactivated with code reason code Data not required.	Kayla Flege (b) (4)	19 Nov 2020 22:47:11
User entered empty.	Kayla Flege (b) (4)	11 Sep 2020 14:36:34

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:16:35

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Kayla Flege (b) (4)	19 Nov 2020 22:48:09
DataPoint inactivated with code reason code Data not required.	Kayla Flege (b) (4)	19 Nov 2020 22:47:11
User entered empty.	System	11 Sep 2020 14:36:34

US3272260

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:16:35

Severity

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:20:05
User entered 'Grade 1/Mild (Grade 1/Mild)' reason for change: Data Entry Error	Kayla Flege (b) (4)	19 Nov 2020 22:51:18
DataPoint activated with code reason code Data required.	Kayla Flege (b) (4)	19 Nov 2020 22:48:09
DataPoint inactivated with code reason code Data not required.	Kayla Flege (b) (4)	19 Nov 2020 22:47:11
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	1 Nov 2020 01:57:58
Query 'Data is required. Please complete.' answered with 'UPDATED' (Site from System).		9 Nov 2020 22:12:42
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 22:12:08
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 22:12:08
User entered 'Grade 1/Mild (Grade 1/Mild)'	Kayla Flege (b) (4)	11 Sep 2020 14:36:34

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:16:35

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:20:05
User entered 'No (N)' reason for change: Data Entry Error	Kayla Flege (b) (4)	19 Nov 2020 22:51:18
DataPoint activated with code reason code Data required.	Kayla Flege (b) (4)	19 Nov 2020 22:48:09
DataPoint inactivated with code reason code Data not required.	Kayla Flege (b) (4)	19 Nov 2020 22:47:11
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 01:57:57
Query 'Data is required. Please complete.' answered with 'UPDATED' (Site from System).		09 Nov 2020 22:12:45
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 22:12:08
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 22:12:08
User entered 'No (N)'	Kayla Flege (b) (4)	11 Sep 2020 14:36:34

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:16:35

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:20:05
DataPoint activated with code reason code Data required.	Kayla Flege (b) (4)	19 Nov 2020 22:48:09
DataPoint inactivated with code reason code Data not required.	Kayla Flege (b) (4)	19 Nov 2020 22:47:11
User entered '0'	Kayla Flege (b) (4)	11 Sep 2020 14:36:34

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:16:35

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:20:05
DataPoint activated with code reason code Data required.	Kayla Flege (b) (4)	19 Nov 2020 22:48:09
DataPoint inactivated with code reason code Data not required.	Kayla Flege (b) (4)	19 Nov 2020 22:47:11
User entered '0'	Kayla Flege (b) (4)	11 Sep 2020 14:36:34

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:16:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:20:05
DataPoint activated with code reason code Data required.	Kayla Flege (b) (4)	19 Nov 2020 22:48:09
DataPoint inactivated with code reason code Data not required.	Kayla Flege (b) (4)	19 Nov 2020 22:47:11
User entered '0'	Kayla Flege (b) (4)	11 Sep 2020 14:36:34

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:16:35

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:20:05
DataPoint activated with code reason code Data required.	Kayla Flege (b) (4)	19 Nov 2020 22:48:09
DataPoint inactivated with code reason code Data not required.	Kayla Flege (b) (4)	19 Nov 2020 22:47:11
User entered empty.	Kayla Flege (b) (4)	11 Sep 2020 14:36:34

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:16:35

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:20:05
DataPoint activated with code reason code Data required.	Kayla Flege (b) (4)	19 Nov 2020 22:48:09
DataPoint inactivated with code reason code Data not required.	Kayla Flege (b) (4)	19 Nov 2020 22:47:11
User entered empty.	Kayla Flege (b) (4)	11 Sep 2020 14:36:34

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:16:35

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:20:05
DataPoint activated with code reason code Data required.	Kayla Flege (b) (4)	19 Nov 2020 22:48:09
DataPoint inactivated with code reason code Data not required.	Kayla Flege (b) (4)	19 Nov 2020 22:47:11
User entered empty.	Kayla Flege (b) (4)	11 Sep 2020 14:36:34

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Folder: Adverse Events

Form: Adverse Events (2)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:20:05
DataPoint activated with code reason code Data required.	Kayla Flege (b) (4)	19 Nov 2020 22:48:09
DataPoint inactivated with code reason code Data not required.	Kayla Flege (b) (4)	19 Nov 2020 22:47:11
User entered empty.	Kayla Flege (b) (4)	11 Sep 2020 14:36:34

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Folder: Adverse Events

Form: Adverse Events (2)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:20:05
DataPoint activated with code reason code Data required.	Kayla Flege (b) (4)	19 Nov 2020 22:48:09
DataPoint inactivated with code reason code Data not required.	Kayla Flege (b) (4)	19 Nov 2020 22:47:11
User entered '0'	Kayla Flege (b) (4)	11 Sep 2020 14:36:34

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Folder: Adverse Events

Form: Adverse Events (2)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:20:05
DataPoint activated with code reason code Data required.	Kayla Flege (b) (4)	19 Nov 2020 22:48:09
DataPoint inactivated with code reason code Data not required.	Kayla Flege (b) (4)	19 Nov 2020 22:47:11
User entered '0'	Kayla Flege (b) (4)	11 Sep 2020 14:36:34

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Folder: Adverse Events

Form: Adverse Events (2)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:20:05
DataPoint activated with code reason code Data required.	Kayla Flege (b) (4)	19 Nov 2020 22:48:09
DataPoint inactivated with code reason code Data not required.	Kayla Flege (b) (4)	19 Nov 2020 22:47:11
User entered '0'	Kayla Flege (b) (4)	11 Sep 2020 14:36:34

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:16:35

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:20:05
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Kayla Flege (b) (4)	19 Nov 2020 22:51:18
DataPoint activated with code reason code Data required.	Kayla Flege (b) (4)	19 Nov 2020 22:48:09
DataPoint inactivated with code reason code Data not required.	Kayla Flege (b) (4)	19 Nov 2020 22:47:11
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 01:58:03
Query 'Data is required. Please complete.' answered with 'UPDATED' (Site from System).	(b) (4), (b) (6)	09 Nov 2020 22:12:49
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 22:12:08
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 22:12:08
User entered 'Not Related (NOT RELATED)'	Kayla Flege (b) (4)	11 Sep 2020 14:36:34

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:16:35

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:20:05
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Kayla Flege (b) (4)	19 Nov 2020 22:51:18
DataPoint activated with code reason code Data required.	Kayla Flege (b) (4)	19 Nov 2020 22:48:09
DataPoint inactivated with code reason code Data not required.	Kayla Flege (b) (4)	19 Nov 2020 22:47:11
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 01:58:02
Query 'Data is required. Please complete.' answered with 'UPDATED' (Site from System).	(b) (4), (b) (6)	09 Nov 2020 22:12:54
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 22:12:08
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 22:12:08
User entered 'Not Related (NOT RELATED)'	Kayla Flege (b) (4)	11 Sep 2020 14:36:34

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:16:35

Action taken with investigational product

Audit	User	Time (GMT)
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	26 Apr 2021 14:47:10
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered with 'confirmed correct' (Site from System).	Ashley Bell (b) (4)	19 Apr 2021 18:48:31
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	19 Apr 2021 18:44:45
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	09 Apr 2021 22:04:43
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	09 Apr 2021 22:04:43
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	31 Mar 2021 18:22:37
User closed query 'Per CDM: Response provided as 'Data is Correct', However there's no corresponding Dosing Discontinuation page which reflects this IP withdrawal, so Please review and update Dosing Discontinuation page which reflects the same, else clarify.' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 09:26:57

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Folder: Adverse Events

Form: Adverse Events (2)

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Action taken with investigational product

Audit	User	Time (GMT)
Query 'Per CDM: Response provided as 'Data is Correct', However there's no corresponding Dosing Discontinuation page which reflects this IP withdrawal, so Please review and update Dosing Discontinuation page which reflects the same, else clarify. ' answered with 'Subject did not receive 2nd dose of IP until Open label portion of study at the time of AE the 2nd dose was discontinued per protocol at that time' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 17:59:48
User opened query 'Per CDM: Response provided as 'Data is Correct', However there's no corresponding Dosing Discontinuation page which reflects this IP withdrawal, so Please review and update Dosing Discontinuation page which reflects the same, else clarify. ' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 11:52:35
User closed query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in dosing discontinuation if applicable. Review and update. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 11:52:35
Query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in dosing discontinuation if applicable. Review and update. Else, clarify. ' answered with 'Date is correct' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 16:02:57
User opened query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in dosing discontinuation if applicable. Review and update. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	04 Jan 2021 04:12:15
User closed query 'PV Query: Please clarify action taken with IP with regards to second scheduled vaccine administration. If patient did not receive second dose, please update action taken to withdrawn.' (Site from Safety).	(b) (4), (b) (6)	03 Dec 2020 17:54:30

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Action taken with investigational product

Audit	User	Time (GMT)
Query 'PV Query: Please clarify action taken with IP with regards to second scheduled vaccine administration. If patient did not receive second dose, please update action taken to withdrawn.' answered with 'updated' (Site from Safety). DataPoint Un-verified.	Kayla Flege (b) (4)	01 Dec 2020 18:23:49
	(b) (4)	
	Kayla Flege (b) (4)	01 Dec 2020 18:23:36
	(b) (4)	
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Kayla Flege (b) (4)	01 Dec 2020 18:23:36
	(b) (4)	
User opened query 'PV Query: Please clarify action taken with IP with regards to second scheduled vaccine administration. If patient did not receive second dose, please update action taken to withdrawn.' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:33:49
		20 Nov 2020 19:20:05
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Kayla Flege (b) (4)	19 Nov 2020 22:51:18
	(b) (4)	
DataPoint activated with code reason code Data required.	Kayla Flege (b) (4)	19 Nov 2020 22:48:09
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Kayla Flege (b) (4)	19 Nov 2020 22:47:11
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	1 Nov 2020 01:58:00
Query 'Data is required. Please complete.' answered with 'UPDATED' (Site from System).		9 Nov 2020 22:12:57
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 22:12:08
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 22:12:08
User entered 'None (NONE)'	Kayla Flege (b) (4)	11 Sep 2020 14:36:34
	(b) (4)	

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None

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:20:05
DataPoint activated with code reason code Data required.	Kayla Flege (b) (4)	19 Nov 2020 22:48:09
DataPoint inactivated with code reason code Data not required.	Kayla Flege (b) (4)	19 Nov 2020 22:47:11
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	09 Nov 2020 22:13:10
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 22:13:10
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	09 Nov 2020 22:12:08
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 22:12:08
User entered '1'	Kayla Flege (b) (4)	11 Sep 2020 14:36:34

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:20:05
DataPoint activated with code reason code Data required.	Kayla Flege (b) (4)	19 Nov 2020 22:48:09
DataPoint inactivated with code reason code Data not required.	Kayla Flege (b) (4)	19 Nov 2020 22:47:11
User entered '0'	Kayla Flege (b) (4)	11 Sep 2020 14:36:34

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Form: Adverse Events (2)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:20:05
DataPoint activated with code reason code Data required.	Kayla Flege (b) (4)	19 Nov 2020 22:48:09
DataPoint inactivated with code reason code Data not required.	Kayla Flege (b) (4)	19 Nov 2020 22:47:11
User entered '0'	Kayla Flege (b) (4)	11 Sep 2020 14:36:34

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	03 Dec 2020 17:54:36
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'updated' (Site from Safety).	Kayla Flege (b) (4)	01 Dec 2020 18:23:53
DataPoint Un-verified.	Kayla Flege (b) (4)	01 Dec 2020 18:23:36
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Kayla Flege (b) (4)	01 Dec 2020 18:23:36
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 21:32:25
DataPoint Verified.		20 Nov 2020 19:20:05
User closed query 'Specify sequelae is provided, but Outcome is not Recovered/Resolved with Sequelae. Please correct.' (Site from System).	System	19 Nov 2020 22:55:34
User opened query 'Specify sequelae is provided, but Outcome is not Recovered/Resolved with Sequelae. Please correct.' (Site from System).	System	19 Nov 2020 22:54:47
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	Kayla Flege (b) (4)	19 Nov 2020 22:54:47
User closed query 'Specify sequelae is provided, but Outcome is not Recovered/Resolved with Sequelae. Please correct.' (Site from System).	System	19 Nov 2020 22:54:33
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: Data Entry Error	Kayla Flege (b) (4)	19 Nov 2020 22:54:33
User opened query 'Specify sequelae is provided, but Outcome is not Recovered/Resolved with Sequelae. Please correct.' (Site from System).	System	19 Nov 2020 22:51:18

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EAB) (1725)

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[Outcome](#)

Audit	User	Time (GMT)
User entered 'Unknown (UNKNOWN)' reason for change: Data Entry Error	Kayla Flege (b) (4)	19 Nov 2020 22:51:18
DataPoint activated with code reason code Data required.	Kayla Flege (b) (4)	19 Nov 2020 22:48:09
DataPoint inactivated with code reason code Data not required.	Kayla Flege (b) (4)	19 Nov 2020 22:47:11
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	17 Nov 2020 16:00:10
Query 'Data is required. Please complete.' answered with 'UPDATED' (Site from System).		09 Nov 2020 22:13:00
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 22:12:08
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 22:12:08
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Kayla Flege (b) (4)	11 Sep 2020 14:36:34

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:20:05
User entered empty; reason for change Data Entry Error	Kayla Flege (b) (4)	19 Nov 2020 22:55:34
User entered 'Subject still tested positive at visit 2 but subject is asymptomatic.' reason for change: Data Entry Error	Kayla Flege (b) (4)	19 Nov 2020 22:51:18
DataPoint activated with code reason code Data required.	Kayla Flege (b) (4)	19 Nov 2020 22:48:09
DataPoint inactivated with code reason code Data not required.	Kayla Flege (b) (4)	19 Nov 2020 22:47:11
User entered empty.	Kayla Flege (b) (4)	11 Sep 2020 14:36:34

US3272260

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:16:35

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
User closed query 'PV Query: Please clarify date of day 1 of symptom log. Day 1 states 26 Aug 2020 and day 2 states 29 Aug 2020.' (Site from Safety).	(b) (4), (b) (6)	03 Dec 2020 17:54:44
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	03 Dec 2020 17:54:40
Query 'PV Query: Please clarify date of day 1 of symptom log. Day 1 states 26 Aug 2020 and day 2 states 29 Aug 2020.' answered with 'updated' (Site from Safety).	Kayla Flege (b) (4)	01 Dec 2020 18:24:05
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'no treatment' (Site from Safety).	Kayla Flege (b) (4)	01 Dec 2020 18:23:58
User opened query 'PV Query: Please clarify date of day 1 of symptom log. Day 1 states 26 Aug 2020 and day 2 states 29 Aug 2020.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 21:33:32
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 21:32:41
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:20:05
DataPoint activated with code reason code Data required.	Kayla Flege (b) (4)	19 Nov 2020 22:48:09
DataPoint inactivated with code reason code Data not required.	Kayla Flege (b) (4)	19 Nov 2020 22:47:11

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:16:35

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	11 Sep 2020 14:36:34

US3272260

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:16:35

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Kayla Flege (b) (4)	19 Nov 2020 22:48:09
DataPoint inactivated with code reason code Data not required.	Kayla Flege (b) (4)	19 Nov 2020 22:47:11
User entered '0'	System	11 Sep 2020 14:36:34

US3272260

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:16:35

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	19 Nov 2020 22:51:18
DataPoint activated with code reason code Data required.	Kayla Flege (b) (4)	19 Nov 2020 22:48:09
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Kayla Flege (b) (4)	19 Nov 2020 22:47:11
	(b) (4)	
User entered '0'	System	11 Sep 2020 14:36:34

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:16:35

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Kayla Flege (b) (4)	19 Nov 2020 22:48:09
DataPoint inactivated with code reason code Data not required.	Kayla Flege (b) (4)	19 Nov 2020 22:47:11

US3272260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:16:35

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:09:53
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:19:44
DataPoint Un-verified.		21 Oct 2020 19:58:20
User entered 'Yes (Y)' reason for change: Data Entry Error		21 Oct 2020 19:58:20
DataPoint Verified.		29 Sep 2020 17:11:36
User entered 'No (N)'		26 Aug 2020 15:05:38

US3272260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:16:35

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:19:29
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 20:02:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 20:02:43
Data point term sent to Coder	System	21 Oct 2020 20:01:32
User entered 'Influenza vaccine'	(b) (4), (b) (6)	21 Oct 2020 20:00:43

US3272260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:16:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:19:29
User entered 'Yes (Y)'		21 Oct 2020 20:00:43

US3272260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:16:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:19:29
User entered 'Influenza prevention'		21 Oct 2020 20:00:43

US3272260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:16:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:19:29
User entered '.5'		21 Oct 2020 20:00:43

US3272260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:16:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:19:29
User entered 'mL (mL)'		21 Oct 2020 20:00:43

US3272260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:16:35

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:19:29
User entered empty.		21 Oct 2020 20:00:43

US3272260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:16:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:19:29
User entered 'once (ONCE)'		21 Oct 2020 20:00:43

US3272260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:16:35

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:19:29
User entered empty.		21 Oct 2020 20:00:43

US3272260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:16:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:19:29
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	21 Oct 2020 20:00:43

US3272260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:16:35

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:19:29
User entered empty.		21 Oct 2020 20:00:43

US3272260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:16:35

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:19:29
User entered '29 Sep 2020'		21 Oct 2020 20:00:43

US3272260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:16:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:19:29
User entered '0'		21 Oct 2020 20:00:43

US3272260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:16:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:19:29
User entered 'No (N)'	(b) (4), (b) (6)	21 Oct 2020 20:00:43

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:16:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:19:29
User entered '29 Sep 2020'		21 Oct 2020 20:00:43

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:16:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:19:29
User entered 'No (N)'		21 Oct 2020 20:00:43

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:16:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 20:00:43

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:16:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 20:00:43

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:16:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 20:00:43

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:16:35

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:13
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 17:11:48
User entered 'No (N)'		26 Aug 2020 15:05:28

US3272260

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:16:35

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:01:25
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:43:07
User closed query 'As per IRT and EDC subject received only 1 dose in Part A and is a dosing discontinuation please review and complete the dosing discontinuation form' (Site from CRA).		20 Apr 2021 16:43:02
Query 'As per IRT and EDC subject received only 1 dose in Part A and is a dosing discontinuation please review and complete the dosing discontinuation form' answered with 'updated' (Site from CRA).	Ashley Bell (b) (4)	19 Apr 2021 18:44:52
User entered '23 Sep 2020' reason for change: Data Entry Error	Ashley Bell (b) (4)	19 Apr 2021 18:44:45
User opened query 'As per IRT and EDC subject received only 1 dose in Part A and is a dosing discontinuation please review and complete the dosing discontinuation form' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 23:15:45
User closed query 'Data is required. Please complete.' (Site from System).		14 Apr 2021 18:08:45
Query 'Data is required. Please complete.' answered with 'added in error' (Site from System).	Ashley Bell (b) (4)	09 Apr 2021 22:05:56
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Apr 2021 22:05:51
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	09 Apr 2021 22:05:51
User entered empty; reason for change Data Entry Error	Ashley Bell (b) (4)	09 Apr 2021 22:05:51
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	09 Apr 2021 22:04:43
User entered ' Jan ' (non-conformant).	Ashley Bell (b) (4)	09 Apr 2021 22:04:43
User entered '15 Feb 2021'	Ashley Bell (b) (4)	31 Mar 2021 18:22:37

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:16:35

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:01:25
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:43:07
User closed query 'Per CDM: Per AE Log Line #2, subject did not receive second dose of IP due to confirmed Symptomatic Covid-19. Dosing Discontinuation form is only applicable to Part-A and should be used to indicate dosing discontinuation from Part A of study as per page 8 of v5.0 of CCGs. For Part A only: event of 'Diagnosed COVID-19 by detection of SARS-CoV-2' in Day 1 NP swab or COVID-19 diagnosed prior to Day 29 is an events that constitutes absolute contraindications to any further dosing of the IP to that participant in Part A of study. Please verify and reconcile EDC as appropriate.' (Site from DM).		20 Apr 2021 12:33:41
Query 'Per CDM: Per AE Log Line #2, subject did not receive second dose of IP due to confirmed Symptomatic Covid-19. Dosing Discontinuation form is only applicable to Part-A and should be used to indicate dosing discontinuation from Part A of study as per page 8 of v5.0 of CCGs. For Part A only: event of 'Diagnosed COVID-19 by detection of SARS-CoV-2' in Day 1 NP swab or COVID-19 diagnosed prior to Day 29 is an events that constitutes absolute contraindications to any further dosing of the IP to that participant in Part A of study. Please verify and reconcile EDC as appropriate.'	Ashley Bell (b) (4)	19 Apr 2021 18:44:57
answered with 'updated' (Site from DM).		
User entered 'Due to SARS-COV-2 (COVID)' reason for change: Data Entry Error	Ashley Bell (b) (4)	19 Apr 2021 18:44:45

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:16:35

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
User opened query 'Per CDM: Per AE Log Line #2, subject did not receive second dose of IP due to confirmed Symptomatic Covid-19. Dosing Discontinuation form is only applicable to Part-A and should be used to indicate dosing discontinuation from Part A of study as per page 8 of v5.0 of CCGs. For Part A only: event of 'Diagnosed COVID-19 by detection of SARS-CoV-2' in Day 1 NP swab or COVID-19 diagnosed prior to Day 29 is an events that constitutes absolute contraindications to any further dosing of the IP to that participant in Part A of study. Please verify and reconcile EDC as appropriate.' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 16:34:34
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	14 Apr 2021 18:08:52
Query 'Data is required. Please complete.' answered with 'added in error' (Site from System).	Ashley Bell (b) (4)	09 Apr 2021 22:06:01
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Apr 2021 22:04:43
User entered empty; reason for change Data Entry Error	Ashley Bell (b) (4)	09 Apr 2021 22:04:43
User entered 'Withdrawal of consent by participant (specify) (WITHDRAWAL OF CONSENT)'	Ashley Bell (b) (4)	31 Mar 2021 18:22:37

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:16:35

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)	02 May 2021 15:01:25
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:43:07
User entered empty; reason for change Data Entry Error	Ashley Bell (b) (4)	09 Apr 2021 22:04:43
User entered 'Subject withdrew consent after being unblinded via ePIP.'	Ashley Bell (b) (4)	31 Mar 2021 18:22:37

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:16:35

Date of study discontinuation/completion (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:01:25
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	14 Apr 2021 18:08:47
Query 'Data is required. Please complete.' answered with 'added in error' (Site from System).	Ashley Bell (b) (4)	09 Apr 2021 22:05:39
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Apr 2021 22:05:30
User entered empty; reason for change Data Entry Error	Ashley Bell (b) (4)	09 Apr 2021 22:05:30
User entered '15 Feb 2021'	Ashley Bell (b) (4)	31 Mar 2021 18:23:02

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:16:35

[Reason for discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:01:25
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	14 Apr 2021 18:08:49
Query 'Data is required. Please complete.' answered with 'added in error' (Site from System).	Ashley Bell (b) (4)	09 Apr 2021 22:05:45
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Apr 2021 22:05:30
User entered empty; reason for change Data Entry Error	Ashley Bell (b) (4)	09 Apr 2021 22:05:30
User entered 'Withdrawal of consent by participant (specify) (WITHDRAWAL OF CONSENT)'	Ashley Bell (b) (4)	31 Mar 2021 18:23:02

US3272260

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:16:35

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)	02 May 2021 15:01:25
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered empty; reason for change Data Entry Error	Ashley Bell (b) (4)	09 Apr 2021 22:05:30
User entered 'Subject withdrew consent after being unblinded via ePIP.'	Ashley Bell (b) (4)	31 Mar 2021 18:23:02

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:16:35

If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:01:25
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered empty.	Ashley Bell (b) (4)	31 Mar 2021 18:23:02

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:16:35

If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:01:25
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered empty.	Ashley Bell (b) (4)	31 Mar 2021 18:23:02

US3272260

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:16:35

Date of death (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:01:25
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered empty.	Ashley Bell (b) (4)	31 Mar 2021 18:23:02

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:16:35

[Was autopsy performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:01:25
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered empty.	Ashley Bell (b) (4)	31 Mar 2021 18:23:02

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Folder: SAE USA-US070-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 11 Aug 2021 22:16:35

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 01:54:52
User entered 'USA-US070-2020-MRNA-1273-P301000023'	System	21 Nov 2020 01:54:27

US3272260

Folder: SAE USA-US070-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 11 Aug 2021 22:16:35

Serious

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 01:54:52
User entered 'No (N)'	System	21 Nov 2020 01:54:27

US3272260

Folder: SAE USA-US070-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 11 Aug 2021 22:16:35

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 01:54:52
User entered 'No (N)'	System	21 Nov 2020 01:54:27

US3272260

Folder: SAE USA-US070-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 11 Aug 2021 22:16:35

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 01:54:52
User entered 'No (N)'	System	21 Nov 2020 01:54:27

US3272260

Folder: SAE USA-US070-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 11 Aug 2021 22:16:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 01:54:52
User entered 'No (N)'	System	21 Nov 2020 01:54:27

US3272260

Folder: SAE USA-US070-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 11 Aug 2021 22:16:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 01:54:52
User entered 'No (N)'	System	21 Nov 2020 01:54:27

US3272260

Folder: SAE USA-US070-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 11 Aug 2021 22:16:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 01:54:52
User entered 'No (N)'	System	21 Nov 2020 01:54:27

US3272260

Folder: SAE USA-US070-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 11 Aug 2021 22:16:35

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 01:54:52
User entered 'No (N)'	System	21 Nov 2020 01:54:27

US3272260

Folder: SAE USA-US070-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 11 Aug 2021 22:16:35

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 01:54:52
User entered 'Adam'	System	21 Nov 2020 01:54:27

US3272260

Folder: SAE USA-US070-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 11 Aug 2021 22:16:35

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 01:54:52
User entered 'Brosz'	System	21 Nov 2020 01:54:27

US3272260

Folder: SAE USA-US070-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 11 Aug 2021 22:16:35

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 01:54:52
User entered '2444 W. Faidley Ave'	System	21 Nov 2020 01:54:27

US3272260

Folder: SAE USA-US070-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 11 Aug 2021 22:16:35

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 01:54:52
User entered 'Grand Island'	System	21 Nov 2020 01:54:27

US3272260

Folder: SAE USA-US070-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 11 Aug 2021 22:16:35

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 01:54:52
User entered 'NE'	System	21 Nov 2020 01:54:27

US3272260

Folder: SAE USA-US070-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 11 Aug 2021 22:16:35

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 01:54:52
User entered '68803'	System	21 Nov 2020 01:54:27

US3272260

Folder: SAE USA-US070-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 11 Aug 2021 22:16:35

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 17:53:46
User entered 'US'	System	21 Nov 2020 01:54:58

US3272260

Folder: SAE USA-US070-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 11 Aug 2021 22:16:35

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	11 Dec 2020 21:15:01
User entered '2'	System	03 Dec 2020 17:53:58
User entered '1'	System	21 Nov 2020 01:54:58

US3272260

Folder: SAE USA-US070-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 11 Aug 2021 22:16:35

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 01:54:52
User entered 'USA-US070-2020-MRNA-1273-P301000023'	System	21 Nov 2020 01:54:27

US3272260

Folder: SAE USA-US070-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 11 Aug 2021 22:16:35

Serious

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 01:54:52
User entered 'No (N)'	System	21 Nov 2020 01:54:27

US3272260

Folder: SAE USA-US070-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 11 Aug 2021 22:16:35

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 01:54:52
User entered 'No (N)'	System	21 Nov 2020 01:54:27

US3272260

Folder: SAE USA-US070-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 11 Aug 2021 22:16:35

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 01:54:52
User entered 'No (N)'	System	21 Nov 2020 01:54:27

US3272260

Folder: SAE USA-US070-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 11 Aug 2021 22:16:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 01:54:52
User entered 'No (N)'	System	21 Nov 2020 01:54:27

US3272260

Folder: SAE USA-US070-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 11 Aug 2021 22:16:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 01:54:52
User entered 'No (N)'	System	21 Nov 2020 01:54:27

US3272260

Folder: SAE USA-US070-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 11 Aug 2021 22:16:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 01:54:52
User entered 'No (N)'	System	21 Nov 2020 01:54:27

US3272260

Folder: SAE USA-US070-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 11 Aug 2021 22:16:35

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 01:54:52
User entered 'No (N)'	System	21 Nov 2020 01:54:27

US3272260

Folder: SAE USA-US070-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 11 Aug 2021 22:16:35

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 01:54:52
User entered 'Adam'	System	21 Nov 2020 01:54:27

US3272260

Folder: SAE USA-US070-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 11 Aug 2021 22:16:35

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 01:54:52
User entered 'Brosz'	System	21 Nov 2020 01:54:27

US3272260

Folder: SAE USA-US070-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 11 Aug 2021 22:16:35

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 01:54:52
User entered '2444 W. Faidley Ave'	System	21 Nov 2020 01:54:27

US3272260

Folder: SAE USA-US070-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 11 Aug 2021 22:16:35

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 01:54:52
User entered 'Grand Island'	System	21 Nov 2020 01:54:27

US3272260

Folder: SAE USA-US070-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 11 Aug 2021 22:16:35

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 01:54:52
User entered 'NE'	System	21 Nov 2020 01:54:27

US3272260

Folder: SAE USA-US070-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 11 Aug 2021 22:16:35

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 01:54:52
User entered '68803'	System	21 Nov 2020 01:54:27

US3272260

Folder: SAE USA-US070-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 11 Aug 2021 22:16:35

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 17:53:46
User entered 'US'	System	21 Nov 2020 01:54:58

US3272260

Folder: SAE USA-US070-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 11 Aug 2021 22:16:35

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	11 Dec 2020 21:15:01
User entered '2'	System	03 Dec 2020 17:53:58
User entered '1'	System	21 Nov 2020 01:54:58

US3272260

Folder: SAE USA-US070-2020-MRNA-1273-P301000023

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:16:35

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered '20/Nov/2020 20:54'	System	21 Nov 2020 01:54:58

US3272260

Folder: SAE USA-US070-2020-MRNA-1273-P301000023

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:16:35

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.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 17:53:46
User entered 'I'	(b) (4), (b) (6)	21 Nov 2020 01:54:58

US3272260

Folder: SAE USA-US070-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 11 Aug 2021 22:16:35

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 01:54:52
User entered 'USA-US070-2020-MRNA-1273-P301000023'	System	21 Nov 2020 01:54:27

US3272260

Folder: SAE USA-US070-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 11 Aug 2021 22:16:35

Serious

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 01:54:52
User entered 'No (N)'	System	21 Nov 2020 01:54:27

US3272260

Folder: SAE USA-US070-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 11 Aug 2021 22:16:35

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 01:54:52
User entered 'No (N)'	System	21 Nov 2020 01:54:27

US3272260

Folder: SAE USA-US070-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 11 Aug 2021 22:16:35

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 01:54:52
User entered 'No (N)'	System	21 Nov 2020 01:54:27

US3272260

Folder: SAE USA-US070-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 11 Aug 2021 22:16:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 01:54:52
User entered 'No (N)'	System	21 Nov 2020 01:54:27

US3272260

Folder: SAE USA-US070-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 11 Aug 2021 22:16:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 01:54:52
User entered 'No (N)'	System	21 Nov 2020 01:54:27

US3272260

Folder: SAE USA-US070-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 11 Aug 2021 22:16:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 01:54:52
User entered 'No (N)'	System	21 Nov 2020 01:54:27

US3272260

Folder: SAE USA-US070-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 11 Aug 2021 22:16:35

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 01:54:52
User entered 'No (N)'	System	21 Nov 2020 01:54:27

US3272260

Folder: SAE USA-US070-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 11 Aug 2021 22:16:35

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 01:54:52
User entered 'Adam'	System	21 Nov 2020 01:54:27

US3272260

Folder: SAE USA-US070-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 11 Aug 2021 22:16:35

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 01:54:52
User entered 'Brosz'	System	21 Nov 2020 01:54:27

US3272260

Folder: SAE USA-US070-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 11 Aug 2021 22:16:35

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 01:54:52
User entered '2444 W. Faidley Ave'	System	21 Nov 2020 01:54:27

US3272260

Folder: SAE USA-US070-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 11 Aug 2021 22:16:35

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 01:54:52
User entered 'Grand Island'	System	21 Nov 2020 01:54:27

US3272260

Folder: SAE USA-US070-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 11 Aug 2021 22:16:35

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 01:54:52
User entered 'NE'	System	21 Nov 2020 01:54:27

US3272260

Folder: SAE USA-US070-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 11 Aug 2021 22:16:35

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 01:54:52
User entered '68803'	System	21 Nov 2020 01:54:27

US3272260

Folder: SAE USA-US070-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 11 Aug 2021 22:16:35

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 17:53:46
User entered 'US'	System	21 Nov 2020 01:54:58

US3272260

Folder: SAE USA-US070-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 11 Aug 2021 22:16:35

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	11 Dec 2020 21:15:01
User entered '2'	System	03 Dec 2020 17:53:58
User entered '1'	System	21 Nov 2020 01:54:58

US3272260

Folder: SAE USA-US070-2020-MRNA-1273-P301000023

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:16:35

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered '03/Dec/2020 17:53'	System	03 Dec 2020 17:53:58

US3272260

Folder: SAE USA-US070-2020-MRNA-1273-P301000023

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:16:35

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.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 21:14:45
User entered 'I'		03 Dec 2020 17:53:58

US3272260

Folder: SAE USA-US070-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 11 Aug 2021 22:16:35

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 01:54:52
User entered 'USA-US070-2020-MRNA-1273-P301000023'	System	21 Nov 2020 01:54:27

US3272260

Folder: SAE USA-US070-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 11 Aug 2021 22:16:35

Serious

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 01:54:52
User entered 'No (N)'	System	21 Nov 2020 01:54:27

US3272260

Folder: SAE USA-US070-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 11 Aug 2021 22:16:35

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 01:54:52
User entered 'No (N)'	System	21 Nov 2020 01:54:27

US3272260

Folder: SAE USA-US070-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 11 Aug 2021 22:16:35

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 01:54:52
User entered 'No (N)'	System	21 Nov 2020 01:54:27

US3272260

Folder: SAE USA-US070-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 11 Aug 2021 22:16:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 01:54:52
User entered 'No (N)'	System	21 Nov 2020 01:54:27

US3272260

Folder: SAE USA-US070-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 11 Aug 2021 22:16:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 01:54:52
User entered 'No (N)'	System	21 Nov 2020 01:54:27

US3272260

Folder: SAE USA-US070-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 11 Aug 2021 22:16:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 01:54:52
User entered 'No (N)'	System	21 Nov 2020 01:54:27

US3272260

Folder: SAE USA-US070-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 11 Aug 2021 22:16:35

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 01:54:52
User entered 'No (N)'	System	21 Nov 2020 01:54:27

US3272260

Folder: SAE USA-US070-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 11 Aug 2021 22:16:35

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 01:54:52
User entered 'Adam'	System	21 Nov 2020 01:54:27

US3272260

Folder: SAE USA-US070-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 11 Aug 2021 22:16:35

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 01:54:52
User entered 'Brosz'	System	21 Nov 2020 01:54:27

US3272260

Folder: SAE USA-US070-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 11 Aug 2021 22:16:35

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 01:54:52
User entered '2444 W. Faidley Ave'	System	21 Nov 2020 01:54:27

US3272260

Folder: SAE USA-US070-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 11 Aug 2021 22:16:35

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 01:54:52
User entered 'Grand Island'	System	21 Nov 2020 01:54:27

US3272260

Folder: SAE USA-US070-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 11 Aug 2021 22:16:35

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 01:54:52
User entered 'NE'	System	21 Nov 2020 01:54:27

US3272260

Folder: SAE USA-US070-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 11 Aug 2021 22:16:35

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 01:54:52
User entered '68803'	System	21 Nov 2020 01:54:27

US3272260

Folder: SAE USA-US070-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 11 Aug 2021 22:16:35

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 17:53:46
User entered 'US'	System	21 Nov 2020 01:54:58

US3272260

Folder: SAE USA-US070-2020-MRNA-1273-P301000023

Form: Safety Report Form

Generated On: 11 Aug 2021 22:16:35

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	11 Dec 2020 21:15:01
User entered '2'	System	03 Dec 2020 17:53:58
User entered '1'	System	21 Nov 2020 01:54:58

US3272260

Folder: SAE USA-US070-2020-MRNA-1273-P301000023

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 22:16:35

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered '11/Dec/2020 13:15'	System	11 Dec 2020 21:15:01

US3272260

Folder: SAE USA-US070-2020-MRNA-1273-P301000023

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 22:16:35

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.	Adam Brosz (b) (4)	29 Apr 2021 23:23:55
User entered 'I'	(b) (4), (b) (6)	11 Dec 2020 21:15:01